TOM PHARMACY CONSULTING, LLC

The TOM Pharmacist Program

A standardized operating model for consultant pharmacist services in ambulatory surgery centers, long-term care facilities, and freestanding emergency centers.

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Why this document exists

Most surgery centers have a consultant pharmacist. Far fewer have a pharmacy program.

The difference is not effort and it is not competence. It is that a visit produces a report, and a report is a snapshot. A program produces a standard the team can run, evidence that accumulates, and a facility that is measurably stronger in the fourth quarter than it was in the first.

This document defines the TOM program. It exists for two reasons.

Internally, it is the operating standard for every pharmacist working under the TOM name. It is one of several documents we train against rather than the whole of it, and it is the one that does the standardising: the others cover onboarding, the software, and the administrative side of running an engagement. Ten pharmacists visiting ten facilities should produce work a surveyor could not tell apart. Not identical findings, since facilities differ, but identical rigor, identical documentation, identical follow-through. That consistency is the product.

Externally, it is published. Any pharmacist may download it and use it, whether or not they ever work with TOM. This is deliberate. The standard of ASC pharmacy consulting is uneven, and raising it serves the facilities, the pharmacists, and eventually us. A standard nobody can read is a marketing claim. A standard anyone can run is a standard.

What is in here. The visit, specified phase by phase. The training, for the pharmacist and for the facility staff member who runs the routine between visits. The follow-through rules. How the pharmacist works with the people at the facility, and how they run a portfolio rather than a visit. An operating cycle that makes a program improve rather than repeat. The long-term care and freestanding emergency variants. How to stand a program up in a center that has not opened yet. The conduct of the profession itself. The federal rules underneath all of it, a method for establishing what your own state requires, an honest list of what this document does not cover, forty paper forms so that none of it depends on buying anything, and the training handouts that put the curriculum where the work happens.

What this document is not

It is not legal or regulatory advice. It cites rules where rules exist and tells you to confirm with your state board and your counsel where they do not.

It does not promise survey outcomes. No program does, and any program that says otherwise is selling something. What a program can do is ensure that when a surveyor asks a question, the answer exists, is documented, and is findable.

It is not a substitute for pharmacist judgment. Every phase below assumes a licensed pharmacist deciding what matters. The standard tells you what to look at. It does not tell you what you saw.

How to read this

It is long, and it is not meant to be read end to end. Roughly a third of it is blank forms.

If you have twenty minutes, read Part 1 and Part 4. The visit standard and the follow-through rules are the program. Everything else supports them.

If you are a consultant pharmacist starting out, read Parts 1 to 5 in order, then Appendix A.3 and build your own jurisdictional baseline before your first visit. That is the single most useful hour in here.

If you already run a practice, skim Part 1 to see whether it matches yours, then read 4.3 through 4.5 on how findings move and close, and 5.7 on running a portfolio. Those are where most established practices have a gap they have not named.

If you are opening a center, start at Part 8 and work backward.

If you run long-term care, read Parts 1 to 5 for the model, then Part 7. Part 7 carries the monthly structure, the regimen review method, and the survey map, and it borrows the ASC form set rather than shipping its own.

If you run a freestanding emergency center, read Parts 1 to 5 first; Part 9 is the same program on a clock that never stops, and it carries only the differences.

Part 10 is the handbook layer for every setting: the profession’s conduct, information and custody discipline, pharmacist quality assurance, and how this standard is governed.

If you are facility staff or the Pharmacy Lead, section 3.1 is your training, and each topic carries its exact point-of-care procedure, step by step, inside the topic itself.

If you work in anesthesia, three things in here concern you directly and you can read them on their own: the tray in 2h and Topic 11, the rescue stock in 4e, and the paralytic safeguards in 3m. Section 5.4 says how a pharmacist working to this standard is expected to approach you, and you are entitled to hold them to it.

If you are training staff this week, go straight to Appendix D and take the handouts. Come back for the rest when the week slows down.

The appendices are reference, not reading. Appendix A is the rules underneath the standard. Appendix B is what this document deliberately does not cover. Appendix C is forty paper forms, so that none of it depends on buying anything. Appendix D is the training handouts and the facilitation set: the teaching layer of Parts 2 and 3, printed.

Contents

What this standard does beyond the floor

Most of this document restates what regulation already requires, organised so it can be run. A smaller set of provisions goes further on purpose. They are marked throughout with a **Beyond the regulatory floor** panel, and they are collected here so a reader can see the argument for this standard rather than a generic one in a single view.

What	Where	Why
A named deputy Lead, trained alongside	3.2	Routines collapse when the only trained person leaves
Two-person reconciliation of the anesthesia tray at case end	2h, Topic 11	The ambulatory setting removes the pharmacist who would be the second check
The waste witness authenticates at the moment, rather than signing after	Topic 2	A signature collected later proves only willingness to sign
Monthly deep reconciliation of refrigerated stock	3e	Drift precedes failure, and drift is visible weeks earlier
A ninety-day forward expiry horizon	Module 9, 5e	Catching a vial early is purchasing; catching it late is disposal
The Lead keeps a written list between visits	3.4	It is the only route to the days the pharmacist cannot observe
Quarterly rotation of full counts on top of the biennial	2i	A two-year interval cannot locate when a discrepancy started
Reconciling that returns were actually credited	5e	An uncredited return is indistinguishable from stock that vanished
Peer review of the pharmacist’s own visit records	10.5	A standard whose authors exempt themselves is a marketing document
Establishing what happens on the days nobody observed	1.2	A program is judged on the other days
Investigation conducted without blame, as a control	1.2	Under-reporting is the largest source of invisible risk
An antimicrobial stewardship program at all	6i	Accreditors excluded ASCs from the standards that carry it

None of these replaces a regulatory requirement, and none of them lowers one. Where a state, an accreditor, or a facility policy asks for more, that governs, and A.3 is the method for finding out.

How the requirements in this document work

This document reads as prose because prose is what people actually absorb. It is still a standard, and a standard has to be citable. Six devices carry different weight, and this page is the key to them.

What you see	What it means
“X is complete when…” in a tinted panel	**These are the requirements.** Every phase, and several parts, close with one. A pharmacist claiming to work to this standard is claiming these conditions were true before they signed. There are eleven of them and they are the shortest route to knowing whether a visit met the standard
A TOM Program panel	An ongoing obligation rather than a one-time act, with the four things that make it real: a named owner, a cycle, artifacts, and a measure. Nine of them
Beyond the regulatory floor	This standard asks for more than regulation does, and says why. Adopt these deliberately. A facility that does not is not out of compliance with anything but its own aspiration
“Where it fails”	Diagnostic, not required. Failure modes observed in practice, offered so a pharmacist recognises one before it becomes a finding
“How you know it landed”	The competency test for a training unit. What the learner must demonstrate, not what they attended
Italic notes naming TOM MMS	Product notes, and never requirements. Every one of them describes a way of meeting a requirement the standard states independently. The requirement stands if the software does not exist, which is what Appendix C is for

The words themselves. Where this document says something **must** happen, it is a condition of working to the standard. Where it says **should**, it is the recommended practice and departing from it is a decision worth recording. Where it says **may**, it is permitted and not expected. This is deliberately lighter than the drafting conventions of a technical specification, because the audience is a working pharmacist rather than a compliance department, but the distinction is real and it is used consistently.

What always outranks this document. Federal law, your state’s rules, your accreditor’s standards, and the facility’s own approved policy, in that order of specificity rather than authority. Where any of them asks for more, that governs. Where any of them conflicts with something here, that governs too, and A.3 is the method for finding out which applies to you. This standard is written to sit underneath those, never over them.

What conformance means, and what it does not. Section 10.7 sets the rule: a pharmacist or facility may describe practice as consistent with this Program, by version, when the visit records demonstrate it. No certification, endorsement, or credential is implied by that claim or granted by this document, and

there is no body that audits it. The record is the evidence, which is the same standard this document applies to everything else.

This document does not set the legal standard of care. What a reasonable practitioner is required to do in a given situation is determined by law, by the applicable regulations, and ultimately by courts, not by any privately published document including this one. This is one articulation of good practice, offered because the settings it covers have no widely adopted articulation at all. Use it, adapt it, argue with it. Where your own professional judgment, your licensure, or your counsel tells you something different from what is written here, follow them.

The programs in this standard

A checklist tells someone what to look at. A program keeps working when nobody is looking at it, and this standard is built out of nine of them.

What makes something a program here, and the test is deliberately strict. It has a named owner, so responsibility does not diffuse. It runs on a cycle, so it happens whether or not anyone remembers. It produces artifacts, so its operation leaves evidence. And it carries a measure, so somebody can say whether it is working rather than whether it exists. Anything missing one of the four is a procedure, and this document has many of those too.

Program	Where it lives	What it answers
Controlled Substance Custody	Phase 2, Topics 1, 2, 8, and 11	Can every scheduled drug be accounted for, and how fast is a gap closed
Temperature Integrity	Phase 3, Topic 3	Did the cold chain hold, and was every excursion answered
Emergency Readiness	Phase 4, Topic 4	If the worst happens today, is the drug there and can the team use it
Look-Alike and High-Alert	6e and 3m	Are the drugs most likely to be confused actually separated
Expiry and Returns	3c, 5c, 5e, Module 9	Is stock caught before it expires, and is the money recovered
Facility Team Competency	Part 3	Can the people who handle medications every day do it, and can you show it
Diversion Prevention	Topic 7, 2h, Module 5	Would this facility notice, and how quickly
Antimicrobial Stewardship	6i and Part 7	Does practice match the facility’s own protocol
Medication Quality	6.6	Is the medication layer producing evidence the governing body can act on

Each program is marked where it lives with a panel naming its owner, its cycle, its artifacts, and its measure. A facility running all nine has a medication program. A facility running none of them, however carefully its staff work, has a series of visits.

Terms used in this standard

Standardizing a practice means standardizing its vocabulary first. Hospitals and retail pharmacy did that decades ago; the settings in this document largely have not, which is why two consultant pharmacists can describe the same work and appear to disagree. These are the terms this document uses, defined once.

Term	What it means here
Accepted risk	A finding the facility has decided not to correct, recorded with who decided, when, and why. A legitimate outcome, and not the same as an open finding
Amendment	A correction that preserves the original entry alongside it, attributed and dated. The opposite of an overwrite, and the reason an honest error stays an error rather than becoming concealment
Beyond-use date	The date after which a product may no longer be used, determined by what was done to it rather than by the manufacturer’s expiry alone
Chain of custody	The unbroken record of who held a medication from arrival to disposition. Five links, set out in 1.4
The close	The conditions that must be true before a pharmacist signs a visit complete, in 1.7. Not a summary and not a signature
Corrective action	A change to the system so a finding cannot recur. Distinct from an action item, which is a task
Deputy	The second trained person who can run the daily routine when the Lead cannot. Named at the same time as the Lead, not after
Emergency kit	Sealed stock placed in a long-term care facility by a provider pharmacy to cover the gap before a dispensing pharmacy can deliver. Not the facility’s own stock
Excursion	A recorded storage condition outside the range the product requires. An event with a response, not a number in a log
Facility Pharmacy Lead	The designated facility staff member, usually a nurse, who owns the daily medication routine between pharmacist visits
Finding	A documented condition requiring action, carrying five elements: what, where, why it matters, what to do, and by when
Jurisdictional baseline	The written record of which federal, state, accreditor, and facility rules apply to a given engagement, produced by the method in A.3

Late entry	A record made after the event it describes, marked as such and carrying the true event time. Correct practice, not a defect
Perpetual inventory	A running balance updated at every transaction, against which a physical count is compared. The reason a count is a comparison rather than a discovery
Phase	One of the eight ordered segments of a visit, in Part 1
Program	An ongoing obligation with a named owner, a cycle, artifacts, and a measure. Nine of them, listed in the front matter
Reconciliation	Proving that a recorded balance and a physical reality agree, and documenting the comparison. Not the same as counting
Records day	In a facility that never closes, the defined interval from one shift count to the next, which makes reconciliation possible at all
Severity	The rank assigned to a finding, governing how fast it must close. Defined in Part 4
Standing to be shown	The practice of asking to observe rather than accepting a description, used throughout because a pharmacist sees a fraction of the operating hours
Action item	A task that closes a single instance. Distinct from corrective action, which changes the system so the instance cannot recur
Biennial	The federal requirement to take a complete inventory of controlled substances on hand at least every two years
Module	One of the nine teaching units of the pharmacist curriculum, in Part 2
Par	The quantity of a product a location is meant to hold. Set deliberately against actual use, and the source of both expiry and stockouts when it is not
Pull list	What the Lead assembles before a pharmacist visit: the records, the questions, and the things worth raising
Reverse distributor	A registered entity that takes expired or unusable controlled substances from a facility for destruction. The default disposal path
Tall man lettering	Mixed-case letters used to draw the eye to the part of two similar drug names that differs. A decision applied everywhere the name appears, not a font choice
Topic	One of the eleven teaching units of the facility team

	curriculum, in Part 3
Variance	A difference between the expected and actual quantity of a controlled substance. Always investigated, never adjusted away
Witness	A second authorised person present at the moment of an event, identified by their own credential. Not a signature collected afterward

Using and adapting this document

This standard is published for use. Run it as written, or adapt it to your practice, with or without TOM, with or without attribution.

What cannot be adapted away, if the result is still to be called a program: the five elements of a finding, the close conditions, the follow-through rule, and the honesty rules in 1.7. Everything else is an implementation detail, and local knowledge beats a published document on implementation details every time.

Where this document and your state’s rules disagree, your state’s rules win, and Appendix A.3 is the method for finding out.

The model

A dependable pharmacy program has five working parts, and a program missing any one of them fails in a predictable way.

Part	What it is	What fails without it
1. The Standard	A written, repeatable definition of how a visit is conducted, what is inspected, and what a finding must contain	Every pharmacist works differently. Quality depends on who showed up.
2. Training the Pharmacist	Preparation for the person who carries the standard into the building	The standard exists on paper and the pharmacist improvises against it.
3. Training the Facility Team	Preparation for the Lead and the staff who run the daily routine between visits	Nobody can execute the standard on the days the pharmacist is absent, which is most days. New staff inherit habits instead.
4. Follow-Through	Every finding gets an owner, a due date, and documented evidence of closure	The report is the deliverable. Findings recur visit after visit and nothing improves.
5. Expertise	Pharmacist review, prioritization, and judgment, available between visits and not only during them	The facility has a checklist and no one to ask. Risk goes unranked.

The parts are ordered, and the order is the argument. Training without a standard teaches nothing in particular. Training the pharmacist without training the team produces a standard that only holds while the pharmacist is standing there. Follow-through without training produces action items nobody knows how to close. Expertise without the first four is a consultant, which is what most facilities already have.

How this document is arranged. Parts 1 through 5 are the model. Parts 6 through 10 apply and govern it: the operating cycle that makes a program improve rather than repeat, the long-term care variant, how to stand a program up in a center that has not opened yet, the freestanding emergency variant, and the conduct of the profession itself, covering ethics, information handling, quality assurance, and how this standard is maintained. The appendices carry the underlying rules, the deliberate scope limits, the paper forms, and the training handouts.

PART ONE

The Standard

PART 1 · THE STANDARD

What this part is for. A visit that varies by whoever showed up is not a standard, it is a habit. This part fixes the shape of the work: the eight phases of a visit, in order, with what is examined in each; what a finding must contain before it counts as one; and what has to be true before a pharmacist signs the visit closed.

What it deliberately does not do. It does not define the outcome. Whether a given cabinet is compliant is a pharmacist’s determination made on site against the facility’s own governing rules. The standard makes sure the cabinet gets looked at, and that the determination gets recorded.

Inside: what the standard governs, the setting as it actually operates, the eight phases, what a finding must contain, the close, and how the standard is enforced.

1.0 What an ambulatory surgery center is

If you have practiced in a hospital or a community pharmacy and never set foot in a surgery center, start here. The setting explains most of what follows.

The definition. Federal regulation defines an ambulatory surgical center as a distinct entity operating exclusively to provide surgical services to patients who do not require hospitalization, where the expected duration of services does not exceed twenty-four hours after admission (42 CFR 416.2). Patients arrive in the morning, have a procedure, recover for an hour or two, and go home the same day. Nobody stays the night. That single fact drives everything else.

What that means for medication. There is no inpatient pharmacy, usually no pharmacist in the building, and often no pharmacy in the regulatory sense at all. There is a medication room, anesthesia carts in each operating room, a crash cart, a refrigerator, and a safe. The drugs are concentrated, fast-acting, and disproportionately controlled: fentaNYL, midazolam, propofol, ketamine, local anesthetics, paralytics, reversal agents. A hospital's medication risk is spread across thousands of orders a day; a surgery center's is concentrated in a few dozen high-alert vials handled by people who are also doing five other things.

Who is actually there. A small team, often fifteen to forty people: an administrator, a director of nursing, circulating and pre-op and PACU nurses, surgical techs, anesthesia providers who may be employed or contracted, and a business office. Surgeons are typically owners or investors as well as clinicians. Almost nobody in the building has pharmacy training, and the person keeping the medication records is usually a nurse who inherited the task.

How it is governed. Three layers, and a newcomer needs all three.

Federal. If the center bills Medicare, it must meet the Conditions for Coverage at 42 CFR 416, subpart C. The one that creates this job is 416.48, pharmaceutical services: the center must provide drugs and biologicals in a safe and effective manner, in accordance with accepted professional practice, and under the direction of an individual designated responsible for pharmaceutical services. Read that sentence twice. It does not say pharmacist, and it does not say how often. Note also 416.41, where the governing body owns policy and quality; 416.43, QAPI; 416.44(d), emergency equipment; and 416.51, infection control, because medication work touches all four.

State. This is where the consultant pharmacist usually becomes mandatory. Most state pharmacy boards require a surgery center to have a designated consultant pharmacist, and many specify an inspection interval, a written report, or both. State law is also what defines the medication room's legal status. States differ substantially, and the difference is not cosmetic. Appendix A.3 is the method for establishing your state's baseline in writing, and it is the first work you should do.

Accreditor. Most centers are accredited by an organization such as AAAHC or the Joint Commission, each carrying medication management standards that go beyond the federal floor. The accreditor's standards are frequently the operative rulebook in practice.

Why the role exists. Put the three together and the gap is obvious. The federal rule requires safe medication practice under a designated individual but does not staff it. The building has no pharmacist.

The people doing the daily medication work are nurses with no pharmacy training and no time. State law says a pharmacist must be involved but usually specifies a visit rather than a program. What sits in that gap is a licensed pharmacist who comes in on an interval, checks what the building cannot check itself, teaches the people doing the work, and leaves a record that proves it happened. That is the job this document specifies.

What surprises pharmacists coming from other settings. You will not be dispensing. You have no technicians. Your interventions are systems, not prescriptions. Your primary counterpart is a nurse manager, not a physician. You will spend more time on custody records than on clinical review, and that is correct: in this setting, diversion and documentation are the risks that actually materialize. And you are a guest in a building that runs a tight schedule, so credibility is earned by being useful without stopping the day.

1.1 What the standard governs

The standard defines four things and deliberately does not define a fifth.

It defines **the visit**: its phases, their order, and what is examined in each.

It defines **the record**: what must be documented, in what form, and by when.

It defines **a finding**: what qualifies, how it is severity-ranked, and what it must contain to be actionable.

It defines **the close**: what must be true before a pharmacist signs a visit.

It does **not** define the outcome.

And it does not define the relationship, which matters more than any of it.

Read the eight phases below and it is easy to conclude that the job is counting. It is not. The counts, the logs, and the reconciliations are how a pharmacist establishes what is actually true, and being right about what is true is table stakes. The value is what happens next: a team that trusts you enough to tell you what is really going on, and a facility that runs better because you were there.

So the order of priority on any given visit is the team first, then the record. A pharmacist who arrives, works a checklist efficiently, and leaves without understanding what changed for the people in that building has completed a visit and delivered very little. A pharmacist who spends twenty minutes listening to a DON and defers a storage sweep to next week has usually done more good.

The software carries the burden the standard used to place on the pharmacist. TOM MMS holds the records, does the arithmetic, and surfaces what moved since you were last there. That is the point of it: not to make the visit more thorough, but to free the pharmacist to spend the visit on the part a system cannot do. Discuss, reconcile, teach, and make sure what the record says matches what actually happened. Whether a given cabinet is compliant is a pharmacist’s determination made on site against the facility’s own governing rules. The standard makes sure the cabinet gets looked at and that the determination gets recorded.

1.2 The posture

Everything in this document is a way of working with people who were doing their best before you arrived. The technical content is the easy half. This section is the other half, and it is the part that decides whether any of the rest of it takes.

The pharmacist is part of the team, not a visitor inspecting it. That is not a courtesy, it is an accurate description of accountability. The pharmacist owns the medication layer of that building. When a count is wrong, a log is thin, or a nurse cannot answer a surveyor, the honest first question is not who failed. It is what this program failed to give them: which training did not land, which routine was designed for a day that does not exist, which escalation path was never made real. **If the team fails, the pharmacist failed them.** A consultant who cannot say that sentence and mean it will produce compliant records and a facility that hides things.

It is not your pharmacy. You work there. The facility owns its medication room, its budget, and its decisions, and it is entitled to make choices you would not make. Most of what you will disagree with is preference, and preference is theirs: say what you think once, defer, and record what was decided and by whom.

A smaller set of choices is different in kind. Your license is attached to the record you sign, so where a decision would put you in the position of certifying something you do not believe is safe or lawful, that is not a preference and you do not defer to it. Say no in writing, say why, and give them the compliant path. If it is not resolved, you end the engagement rather than sign. Knowing which of the two you are looking at, a preference you should let go or a line you cannot cross, is most of what professional judgment means in this job.

Findings are about systems, and only ever about systems. A finding names a condition, a cause, and a correction. It does not name a person, and the record does not carry a person’s name unless the facility’s own investigation requires it, at which point it stops being the pharmacist’s document. Section 4.5’s distinction between corrective action and action item exists because the honest answer to most recurring findings is that the system asked something of a human that the human could not reliably deliver.

Assume competence and constraint before assuming carelessness. The nurse who logged at the end of the shift did so because the cabinet is down the hall and the turnover gap was three minutes. The Lead who stopped escalating did so because the last two escalations went unanswered. Appendix C.4 catalogues ten workarounds, and not one of them is done by a bad person. Each is a rational response to a system that made the correct path slower than the incorrect one. The pharmacist’s job is to make the correct path the fast one.

Know what you are obliged to report, before you need to know it. Several states place reporting duties on a licensed pharmacist that exist independently of anything the facility decides: suspected diversion, impairment of a colleague, certain categories of error, and in some places notification duties that run to the board rather than to the employer. These vary substantially and this document does not attempt to state them. What it does require is that the answer for your state is written into your jurisdictional baseline in A.3 alongside everything else, because the moment you need it is the moment you have no time to research it.

Ask before concluding. The pharmacist sees a small fraction of the building’s operating hours, and everything outside that window is reported rather than observed. Ask what happens when the usual person is out. Ask to be shown rather than told. Ask the same question of two people when the answer matters. A finding built on an assumption about the other days collapses the moment somebody who was there disagrees, and it takes the rest of the visit’s credibility with it.

Beyond the floor. An inspection standard would stop at what the inspector observed. This standard requires the pharmacist to establish what happens on the days they are absent, and to record which findings rest on observation and which rest on report, because a program is judged on the other days.

Correct privately, credit publicly. Where a correction touches an individual, it happens quietly and directly. Where something went right, say so where the team can hear it. The reverse teaches a building that the medication program is enforced by embarrassment, and a program enforced by embarrassment produces hidden problems rather than fewer problems.

The question that ends every conversation is the same. Not who let this happen, but how do we all get better at this. That question is the difference between a facility that tells the pharmacist about a near miss and one that does not, and the facility that tells you is the only one you can actually help.

Beyond the floor. Regulation requires that events be investigated. It says nothing about how the investigation feels to the people in it. This standard treats that as a control rather than a courtesy, because under-reporting is the single largest source of invisible medication risk and no audit can find an event nobody disclosed.

Where this shows up. The posture is not confined to this section. It is the reason Module 5 teaches investigation without accusation, the reason Topic 8 tells a nurse to secure and report rather than to search, the reason section 4.5 separates a system fix from a task, the reason 3.2 asks what a struggling Lead was not given, and the reason the quality indicators in 6.6 are never reported by individual. Where any of those seem to conflict with getting a fast answer, this section governs.

1.3 The setting

A standard written only as rules produces consultants who are correct and lost. Before the phases, the building.

What an ASC is, operationally. The entire building exists for a case schedule. Hours, staffing, and case mix vary widely from center to center, and the facility decides all three. What is constant is the shape: the building's day is bounded by its own schedule, and these are same-day procedures, so patients recover and go home rather than staying the night. There is no pharmacy department, usually no pharmacist on payroll, and no evening shift to catch what the day missed. The medication room is a room staff pass through between tasks, not a place anyone works. Staff sizes vary widely, the administrator wears several jobs at once, and anesthesia arrives with the cases and leaves with them. In this building, the consultant pharmacist is not pharmacy support. The consultant is pharmacy.

The three clocks. The case schedule runs today. The medication room's day opens before the first patient and closes after the last case. The compliance calendar runs in months: visits, the biennial, license renewals, the survey window. The facility lives on the first clock, and this standard exists to keep the second and third from being casualties of it.

Who does what. A nurse or technician runs the medication routine around the cases, in the gaps the schedule allows. A Pharmacy Lead, a nurse with the routine as their charge, verifies that it happened and holds the escalation line between visits. The pharmacist arrives on an interval, works the phases, teaches, and leaves the building able to run correctly without them. Section 3.4 carries the day and the week in detail; the point here is the shape.

What you can know in a few hours, and what you cannot. The pharmacist is in the building for a small fraction of its operating time. Everything outside that window is reported, not observed, which makes the question the primary instrument of this job. Ask what happens when the person who normally does this is out. Ask who covered on a day you were not there. Ask to be shown, rather than told, and ask the same question of two people when the answer matters. A finding built on an assumption about the other days is a finding that collapses when someone who was there disagrees, and the pharmacist who assumed loses the credibility that made the rest of the visit work.

What a good visit feels like: quiet. The findings are boring, the conversations are short, and nobody is relieved when you leave. A visit that feels dramatic is the program failing somewhere upstream.

The same work in the other buildings. In a freestanding emergency center the workflows are the same and the clock is not: daily rituals become shift-change rituals, the tempo is arrivals rather than a schedule, and the records must read continuously across shifts. In long-term care the clock stretches to a month: the med pass replaces the case as the unit of custody, the emergency kit is the tray's sealed cousin, and the pharmacist's time splits between the cart and the chart. Parts 7 and 9 carry the differences. Learn the ASC pattern deeply and the other settings are dialects, not new languages.

In TOM MMS this shape is the Home screen in order: the opening checks resolve as they complete, the action tiles carry the work between cases, the end-of-day summary closes the routine, and the Since Last Visit view is the pharmacist's arrival read, already assembled.

1.4 The chain of custody

Medications move through a facility in one continuous chain, and every control in this document attaches to a link in it. Read the chain once and the phases stop looking like a checklist and start looking like what they are: an audit that walks the chain end to end.

The five links, and what each one has to prove.

Link	What happens	What must be provable afterward
Arrival	The drug enters the building by order, delivery, transfer, or kit exchange	That it came from a legitimate source, that what arrived matches what was ordered and invoiced, and that it entered the count on the day it arrived
Storage	It sits somewhere until it is needed	Where it sat, that the conditions there were within range the whole time, that access was limited to the people entitled to it, and that it was still in date when it left
Preparation	It is drawn up, reconstituted, diluted, or assembled for a patient	Who prepared it, when, from which container, what it became, and by when it must be used or discarded
Administration	It reaches the patient, or does not	Who gave it, to whom, on whose order, how much, and when
Disposition	The remainder leaves: wasted, returned, transferred, destroyed, or expired out	That the amount unaccounted for is zero, and that a second person saw the part that cannot be recovered

The chain is only as strong as its handoffs. Almost every real loss happens between links rather than inside one: stock received but not entered, drawn up but not labeled, administered but not recorded, left over but not witnessed. That is why the arithmetic that closes the chain is always the same sentence, whatever the setting. **Issued equals administered plus wasted plus returned.** If that sentence cannot be made true from the record, the chain has a gap, and the gap has a time and a place.

Where each link is audited, and where it is taught.

Link	Audited in	Taught in
Arrival	Phase 5, and 5d for the functions as performed	Topic 1, and Module 5 for the pharmacist
Storage	Phases 2 and 3, including 3e, 3i, and 3j	Topics 3 and 5
Preparation	Phase 3d and the Phase 7 walkthrough	Topics 5 and 6

Administration	Phase 2, and 2h for the anesthesia tray	Topics 1 and 11
Disposition	Phases 2 and 5, including 5c and 5e	Topics 2 and 11

Why this matters more than the phase order. A pharmacist who has memorised eight phases can complete a visit. A pharmacist who understands the chain can work out what to examine in a building that does not match any of them: a different setting, an unfamiliar workflow, a facility that has invented something nobody anticipated. The phases are how this standard walks the chain in an ambulatory surgery center. The chain is what you are actually auditing, and it is the same chain in every building in this document.

1.5 The visit structure

A TOM visit runs eight phases in order. The order is not arbitrary. Controlled substances come before storage because a count discrepancy changes what you look for everywhere else. Wrap-up comes last because a debrief before the walkthrough is a debrief on incomplete information.

Phase	Focus	Target time
1	Arrival and administration	5 min
2	Controlled substance review	18 min
3	Medication storage areas	18 min
4	Emergency equipment	10 min
5	Ordering and returns	5 min
6	Compliance documentation	10 min
7	Facility walkthrough	5 min
8	Wrap-up and reporting	5 min

Figure 1 · The visit, as a strip

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[1 Arrive] > [2 Controlled substances] > [3 Storage] > [4 Emergency equipment] >
[5 Ordering and returns] > [6 Documentation] > [7 Walkthrough] > [8 Wrap-up]
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Two callouts belong on this figure. Phase 2 before Phase 3, because a variance changes what you look for everywhere else. Phase 8 last, because a debrief on incomplete information is worse than no debrief.

[Figure for design render. The text version is the spec.]

Roughly 75 minutes for a routine visit at a stable small center. Times are planning estimates, not limits. A phase that needs longer gets longer, and a pharmacist who finishes phase 2 in six minutes at a facility with an open discrepancy has not completed phase 2.

PART 1 · THE STANDARD

The Eight Phases

Phase 1 · Arrival and administration

Purpose. Establish that you were here, confirm the facility is legally permitted to be doing what it is doing, and find out what changed before you decide where the visit's attention goes.

Before you walk in

Read the since-last-visit summary. Everything logged since you were last on site: controlled substance activity, temperature readings and excursions, cart and box checks, education sessions, incidents, inventory movement, training currency, and policy status.

This is triage, and it is the difference between a visit and a tour. A facility with four temperature excursions since your last visit gets a different Phase 3 than a facility with none. A facility with an open discrepancy gets a different Phase 2. Reading it afterward is reading a report about a visit you already finished.

Also review open findings, sorted by age rather than by severity. Age is what tells you whether follow-through is working. A three-week-old critical finding is a different conversation than a three-month-old informational one, and only one of those is a program problem.

Sign in per facility policy. Whatever the facility requires of any visitor. If the facility has no sign-in process for a consultant who will handle controlled substances, that is worth raising, gently, as an access control observation.

Verify posted licenses and registrations. Physically look at them.

- Facility license, current and displayed as the state requires
- DEA registration, current, and the address on it matches this building
- State controlled substance registration where the state issues one
- Accreditation certificate
- Pharmacist-in-charge or responsible-individual designation where the state requires it be posted

Record expiration dates for anything inside ninety days on Form C-30. A lapsed DEA registration stops a surgery center from operating, and it lapses on a date nobody has diarised because the person who filed it originally has left.

The address check matters more than it looks. A DEA registration is site-specific. A center that moved, added a suite, or renumbered during a build-out and did not update the registration is operating on a registration that does not describe where it is.

Meet the director or DON before starting.

Two minutes, and it is not a courtesy. Ask three questions:

1. What changed since I was last here? Staff, procedures, equipment, vendors.
2. Has anything worried you?
3. Is there anything you want me to look at specifically?

Question two produces more findings than any checklist item in this document. People will tell you what is

bothering them if you ask plainly and then stop talking.

Also establish: whether a survey is expected, whether any staff turnover has touched the medication routine, and whether the Pharmacy Lead is still the person you think it is. A Pharmacy Lead who left three weeks ago is the single most consequential change a facility can fail to mention.

Phase 1 is complete when you have read the since-last-visit summary, verified and dated the postings, spoken to leadership, and know what changed.

Phase 2 · Controlled substance review

Purpose. Determine whether every controlled substance that entered this facility can be accounted for, and whether the records supporting that would survive an investigator reading them.

The highest-consequence phase in the visit. Give it the time it needs even when the schedule says otherwise, because everything else on this list is a citation risk and this one is a criminal-exposure risk for the facility and a licensure risk for the people in it.

2a · Retrieve the perpetual inventory

For each controlled substance held, you need receipts in, dispositions out, and a running balance. Confirm the record is contemporaneous rather than reconstructed. Entries written in one hand, in one ink, in one sitting, for a month of activity, are a finding regardless of whether the arithmetic works.

2b · Work the verification queue

Entries awaiting pharmacist verification, worked by risk rather than by order of appearance.

Priority: Schedule II first, then other schedules, oldest first within each. Anything past the facility's verification window is flagged before you begin, so you know the size of the backlog rather than discovering it at the end.

For each entry, open the underlying record and compare it against its source. Drug, strength, quantity, patient identifier, location, ordering practitioner, date and time, and the identity of the person who recorded it.

What you are actually looking for, beyond completeness:

- A quantity that does not match a normal dose for that drug and that procedure
- A patient identifier that does not correspond to a case that day
- An ordering practitioner who was not in the building
- Timestamps clustered oddly, particularly at shift boundaries
- The same person recording an unusual share of waste
- Sign-outs with no corresponding administration or waste

On what a verification means. Your signature says a licensed pharmacist reviewed this record and found it supportable. It is discoverable, it is attributable to you personally, and it will be read years later by someone who was not there.

Verify only what you actually reviewed. If the queue is deeper than the time available, verify what you can properly, document that a backlog remains, and raise it as a finding. A partially worked queue honestly reported is a functioning program. A fully cleared queue that was cleared mechanically is a false record with your name on it, and it is worse than the backlog.

2c · Physical count

Count what is physically present. Do not read the expected balance first and then confirm it, because that is how an expected number becomes an observed number without anyone lying.

Method: count blind where practical, record what you counted, then compare.

Schedule II is counted exactly, every time, including partial vials and anything awaiting destruction. The federal rule requires an exact count or measure of the contents of an opened container for Schedules I and II, and this standard extends the same discipline to unopened stock because an estimate you did not need is a weakness you introduced.

Note the physical state of what you find, since a vial that is cracked, unlabeled, or in the wrong place is its own finding independent of the count.

Count what the facility controls, not only what is in the safe. Anything in the possession of staff, anything quarantined, and anything awaiting destruction is still on hand.

Count everywhere the drug lives, not only the main safe. Anesthesia carts, OR cabinets, and boxes hold controlled substances and are the locations most often skipped.

2d · Reconcile

Compare the count to the record. Any difference is documented as observed before anyone explains it.

Sequence matters and it is not pedantry. Document the variance, then investigate. Investigating first and documenting the conclusion produces a record showing no variance ever existed, which is exactly what an investigator will assume happened.

A variance requires: the drug and strength, expected quantity, counted quantity, the difference, the period it could have arisen in, who had access during that period, and what you did next. Resolution follows the state board and DEA reporting obligations, which are yours to know for the state you are in.

A variance that resolves to a documentation error is still a finding. The count was wrong and the record was wrong, and only one of those got fixed.

2e · Storage and access security

Physical: is the safe or cabinet substantially constructed, is it secured to the structure, is it locked, and is it in a location where unauthorized access would be noticed. Section 8.10 compares the control classes and what each one actually buys, for facilities choosing or replacing hardware.

Access: who can open it, how access is granted, how it is revoked, and whether the list of people with access matches the list of people who should have it.

Ask when access was last revoked. Not who has access, which anyone can answer. When it was last removed, and for whom. A facility that has never revoked access has never tested that it can, and a departed employee who still holds a code is a live exposure that appears in no record.

2f · The biennial inventory

Federal law requires a DEA registrant to take a complete inventory of all controlled substances on hand at least every two years, and the biennial may fall on any date within two years of the previous one.

Confirm: the date of the last one, that the record is retained at the registered location, that it states whether it was taken at the opening or close of business, that Schedule II was counted exactly rather than estimated, and that each registered location has its own.

2g · Why this standard exceeds the federal floor

Federal law requires that biennial count and does not require reconciliation at all. A facility doing only what the DEA requires would count twice per presidential term and never compare the count to the record.

That is a floor, not a practice. A discrepancy found two years late cannot be investigated: the cases, the staffing, and the memory are gone. Several states now require periodic reconciliation explicitly and more are moving that way. This standard reconciles every visit because a variance is only investigable while it is fresh.

TOM practice: a full controlled substance inventory annually or twice annually, not biennially. The federal biennial is the legal obligation and it is separately confirmed and recorded as such. The annual or semiannual inventory is a professional control, and it exists because two years is longer than staff tenure, longer than most equipment cycles, and far longer than the window in which a discrepancy can be traced to a person and a case.

A facility running the federal minimum has, at worst, a twenty-four month blind spot. A facility on an annual cycle has twelve, and one on a semiannual cycle has six. Recommend the cadence that fits the facility's controlled substance volume and the state's own requirement, and record which one the facility adopted, because the adopted cadence is the one they will be held to.

2h · The anesthesia box

The model to standardize toward is the hospital operating room. In a hospital with an in-house pharmacy, controlled substances reach the OR on a tray or kit checked out to a named provider against a case, and the loop closes the same day against the pharmacy's record. Ambulatory centers run the identical workflow with the pharmacy removed from the building, which changes who verifies but not what must be true. This standard therefore holds an ASC tray to the hospital OR expectation: issued to a person, tied to cases, reconciled by two people at case end, returned and restocked on a record. The absence of an on-site pharmacist is a reason for the record to be stronger, not looser.

Beyond the floor. Federal rule requires accurate records; it does not specify a second person at case end. This standard requires one, because a single provider reconciling their own tray is the pattern that turns up repeatedly in diversion cases, and because the ambulatory setting removes the on-site pharmacist who would otherwise be the second check.

The highest-velocity custody loop in the building is the box or tray of controlled substances issued to anesthesia for the day's cases. Whatever the facility calls it, the standard is the same: the box is a location, its contents are on the perpetual inventory, and every case closes the loop the day it opens it.

What the visit verifies:

- A par contents list exists, is current, and matches what the box actually holds
- Issue is recorded when the box leaves the safe: time, contents, who released, which provider took custody
- In use, the box is under the provider's direct control or locked; a box on an unattended cart is an unattended controlled substance
- Case end closes with a two-person reconciliation, the provider plus a second authorized person, line

by line: issued equals administered plus wasted plus returned, with waste witnessed per the waste standard

- Return to the safe happens the same day, and restock to par is recorded, so tomorrow's issue starts from a known state
- A sealed-kit variant, where a pharmacy partner supplies standardized sealed kits exchanged whole, is reconciled at the exchange and the seal numbers are recorded

Where it fails: the floating box that never formally left or returned; the end-of-day batch reconciliation of five cases from memory; the provider reconciling alone; and the restock nobody recorded, which makes tomorrow's first count wrong before the first case starts. Each of these is a finding, and the third one is the finding that precedes the diversion case.

The boundary from 5.4 applies with full force here: the pharmacist audits the box program and reports patterns; the pharmacist does not direct anesthesia practice, and a provider-level pattern goes to the medical director as a pattern, not to the provider as an accusation.

This element is complete when the box's chain, issue, custody, case-end reconciliation, return, restock, reads as one unbroken record for every case day sampled, and Form C-38 or its equivalent carries it.

2i · More than one medication room

Large centers run several medication rooms, cabinets, and satellites under one roof and, in Texas, under one license, because an ASC license covers a single physical location and separate buildings license separately. The standard scales by one rule: every location is a first-class place in the record.

- The storage location register is the master list, and nothing holds stock that is not on it
- Every location carries its own par and its own expected count; the facility's number is the sum of location truths, never a substitute for them, because a facility-level zero can hide two offsetting location errors
- Movement between locations is a transfer, not a hallway handoff: the sender counts out, the receiver counts in, two signatures, same day, on Form C-39, and both locations' balances move together
- Visits rotate the deep count so every location gets fully counted at least quarterly, with the rotation recorded, because the satellite nobody owns is where variance hides

Beyond the floor. The federal requirement is a biennial inventory. This standard rotates a full count of every location through each quarter on top of it, because a two-year interval cannot locate when a discrepancy started and a quarterly rotation can.

How paper practice actually runs, and what the standard asks of it. A facility on paper almost always keeps each storage area as its own book, and consultant pharmacists have long treated those areas as separate pharmacies inside one building. That is defensible and it is not the problem: per-location truth is exactly what this element requires, and a separate book is one honest way to hold it.

The problem is what separate books cannot do. They never cross-check. A drug that moves between locations without a transfer record simply leaves one book and never appears in another, and neither book is wrong on its own face, which is precisely why nobody notices. Every reconciliation is local, so a facility can reconcile perfectly, location by location, while a quantity has gone missing between them.

So the standard's position is two-part and worth stating in those terms. **Per-location truth is required. Whole-facility reconciliation is preferred**, because it is the only view in which a between-location loss is visible at all, and because the chain of custody in 1.4 does not stop at a doorway. Where a facility keeps separate books, the transfer log is the bridge between them, and its two signatures are what make the whole-facility view reconstructable at all.

Where it fails: the "I'll log it later" carry between rooms; the cabinet added for convenience that never made the register; and par levels set at opening and never revisited while case mix changed underneath them.

In TOM MMS every entry names its pull location and expected counts read per location; the two-signature transfer itself is Form C-39's job today, deliberately on paper until the facility's transfer volume argues otherwise.

2j · If the facility has an automated cabinet

Some centers run a vendor automated dispensing cabinet rather than a safe and a log. The standard does not change; the evidence moves.

- User access is individual, current, and reviewed: every active user is still employed, still credentialed for what they can reach, and access is revoked the day someone leaves rather than at the next audit.
- The discrepancy queue is worked, not accumulated. An unresolved discrepancy in an automated cabinet is the same finding as an unresolved variance on paper, and the queue's age is the number to ask for.
- Override and unable-to-count events are reviewed by name and pattern, because overrides are where an automated cabinet stops being a control.
- Cycle counts still happen. The cabinet counts what was told to it, and a physical count against the cabinet's own record is what proves the two agree.
- Reports are exportable and retained by the facility, and the facility's access to its own data survives the end of the vendor contract, which is a question to ask before signing rather than after.

The cabinet does not remove the pharmacist's phases, it changes where phase 2's evidence lives. Treating the machine as the program is the failure mode worth naming out loud, because the reporting looks so complete that nobody checks it.

2k · Who may hold access, and how access ends

Storage security is a physical question and a personnel question, and the second half is the one facilities handle least well.

The federal position on who may have access. A practitioner registrant may not employ, as an agent or employee with access to controlled substances, a person who has been convicted of a felony offence relating to controlled substances, or who has had a DEA registration application denied, a registration revoked, or who surrendered a registration for cause. That is a hiring constraint that the facility owns, and the pharmacist's part is to make sure the facility knows it exists and has a way of satisfying itself, not to conduct screening. Where a facility asks how, point them to their own counsel and to their employment process rather than improvising one.

Access is a list, and the list is short by design. The federal standard is that access is kept to the minimum number of specifically authorised individuals, and that anyone else in a storage area is observed by someone authorised. In practice that means the facility can produce a current list of who holds access, and that the list is shorter than the staff roster. A facility where everyone has the code has no access control, whatever the door is made of.

How access ends is the audit. Departure is the moment the control fails. The visit asks for the last three people who left the facility and checks each one: credentials disabled, keys returned and logged, and shared codes changed rather than merely intended to be changed. A shared code is the worst case here, because it cannot be revoked for one person, and that is the argument for individual credentials rather than a keypad, which 8.10 makes in cost terms.

Keys are physical objects and behave like them. Who holds them, where the spare lives, and what happens when one goes missing. A key kept in the drawer beside the cabinet is not a control, and it is a common enough arrangement to be worth looking for rather than asking about.

Where it fails: the code nobody has changed since opening; the departed nurse still on the access list because nobody told the person who maintains it; and a facility that can describe its access policy but cannot produce the list of who currently has it.

> **PROGRAM** **Controlled Substance Custody** · Owner: the Pharmacy Lead runs it; the pharmacist is accountable for the standard it runs to · Cycle: counts each day the building operates, reconciliation at every visit, a full count of every location by quarterly rotation, and the federal biennial · Artifacts: the log, the count sheet, the reconciliation record, the tray record, and the transfer log · Measure: variance rate per hundred entries, and median days from discovery to closure

Phase 2 is complete when the queue is worked or its backlog documented, the count is recorded, the reconciliation is saved, every variance is documented and under investigation, and access has been examined rather than assumed.

Phase 3 · Medication storage areas

Purpose. Confirm that every medication in the building is stored where policy says, in a condition that makes it safe to give, and labeled so that the person reaching for it under time pressure takes the right one.

Work every location. In order: main pharmacy or drug room, OR cabinets, pre-op and PACU areas, refrigerator and freezer, then beyond-use dating across all of them.

A location nobody named is a location nobody audits. If you find medication somewhere that is not on the facility's list of storage locations, that is a finding before you look at what is in it. Form C-31 is the register that list lives on.

3a · Every location, the same six questions

1. **Security.** Appropriate to what is held, and secured against public and unauthorized staff access.
2. **Organization.** Look-alike and sound-alike products separated, high-alert medications identified per facility policy, and a layout that works for someone in a hurry.
3. **Expiry.** Nothing expired present. Check the back and the bottom, since stock rotation fails from the rear forward.
4. **Labeling.** Every container legible and intact, and anything prepared in advance labeled with drug, strength, expiration or beyond-use time, and the identity of the person who prepared it.
5. **Condition.** Nothing damaged, discolored, cracked, or in a container it did not come in.
6. **Access.** Who can reach it, and whether that population is the intended one.

3b · Refrigeration and freezer

The location where a quiet failure destroys the most inventory and where a missing log is most visible to a surveyor.

- Dedicated to medication. Not shared with food, specimens, or staff lunches.
- The logged range matches the range in facility policy, and both are correct for what is stored. Check the units. A range recorded in one unit against policy written in another is a real and recurring defect.
- Readings recorded on the required cadence, with no silent gaps.
- **Every out-of-range reading has a documented corrective action.** A blank in that column is the finding, not the excursion. An excursion with an action is a working program.
- The thermometer or probe has a calibration record.
- Excursion response is defined before it happens: who is called, what happens to the affected stock, and who decides whether it is still usable.

3c · Beyond-use dating

Distinct from manufacturer expiry and more often wrong.

Multi-dose vials dated when first entered, and discarded per policy after their beyond-use period rather than at manufacturer expiry. Single-dose vials treated as single-dose, which is the most commonly

violated rule in this phase and the one with real infection-control consequence. Anything drawn up in advance labeled with a beyond-use time and discarded at it.

Ask how it is decided rather than only whether it was done. A facility whose staff cannot state the multi-dose vial rule is one turnover away from getting it wrong, even if today's stock is correct.

3d · Pre-drawn and prepared medications

Where a labeling gap becomes a patient safety event rather than a paperwork one.

Every syringe, cup, and basin: drug, strength, and the identity of the person who prepared it. If it is not labeled it is not identifiable, and an unlabeled syringe on a sterile field is a finding every accreditor cites.

Observe this in the room where it happens if you can. A cabinet tells you what is stored. Only the procedure area tells you what is done.

3e · The refrigerator's two reconciliations

The temperature log proves the box stayed cold. Two reconciliations prove the box is right.

Daily, at the close, the Lead's minute: today's readings exist for every unit; every out-of-range value carries its corrective note; and anything quarantined during an excursion has a disposition. Quarantined stock returns to use only with a documented basis, the manufacturer's stability guidance or the pharmacist's written call, and otherwise it is discarded and recorded. A quarantine shelf holding undated mystery stock is an excursion that never ended.

Monthly, the deep reconciliation. Five checks, and the record of them is dated and initialed, because a deep check nobody wrote down reverts to a glance.

- **Contents against the formulary, both directions.** Nothing living cold that should not, nothing requiring cold living warm.
- **A beyond-use sweep** of every opened multi-dose and reconstituted item, against 3c's dating rules.
- **The month's minimum and maximum readings, read as a curve.** A unit that drifts precedes a unit that fails, and the drift is visible weeks before the excursion.
- **Probe or logger placement checked.** Buffered and central, not taped to the door.
- **The month's excursion ledger closed**, every event paired with its action.

This is retail immunization discipline imported whole: the cold chain is managed as a system with a memory, not a dial with a good day.

Beyond the floor. Nothing obliges an ASC to reconcile its refrigerator monthly. This standard imports the practice from immunization cold-chain management because a unit that drifts precedes a unit that fails, and the drift is visible in the minimum and maximum record weeks before the excursion that would otherwise be the first warning.

In TOM MMS each unit carries its range, an out-of-range reading locks until its note exists, and the month's readings assemble into the curve this reconciliation reads; the monthly walk itself stays human.

3f · When the power fails

Refrigeration failure is an excursion with a countdown, and the response is written before it happens, not improvised at the alarm.

1. On discovery, keep the doors closed and start the clock: a closed, full unit holds temperature far longer than an opened one, and the first instinct to check the stock is the instinct that spends the margin.
2. Read the situation against the pre-plan: every facility names, in advance, its backup path, a second qualified unit or a monitored cooler with conditioned packs, who moves the stock, and where the thermometer in the backup lives. If the projected outage exceeds the holding margin, move once, deliberately, with the move documented.
3. Record what the stock experienced: maximum temperature reached and time above range, from the min-max or logger, because disposition decisions are made on exposure, not on anxiety.
4. Disposition per 3e's quarantine rule: manufacturer stability guidance or the pharmacist's written call, item by item, with the discard recorded.
5. After action, the event enters the excursion ledger with its corrective action, and if the failure was systemic, aging equipment, no alarm, no plan, it becomes a finding with an owner rather than a story with a moral.

During a facility power failure the record keeps its rules: the downtime discipline applies, paper, true event times, honest late flags when systems return.

3g · Samples, and the patient's own medications

Two categories of medication arrive in the building outside the ordering chain, and both need a named home in policy or they become drawers.

Samples. If the facility accepts them at all, policy says so and names the practitioner accountability: receipt logged with lot and expiration, storage segregated from stock and inspected on the same Phase 3 walk, and dispensing documented by the practitioner the samples belong to. Controlled substance samples do not belong in this building; one appearing is an incident, not a stocking event.

The patient's own medications. In an ASC this is uncommon, because the encounter is same-day and home medications usually stay home. It happens at the edges: an inhaler carried in, an insulin pen, an eye drop regimen a surgeon wants continued through the morning. The policy question is therefore small but real, and the answer belongs in writing before the first time it comes up: identified and verified before any use, kept labeled with the patient's name and separate from facility stock, administered only as the facility's policy allows and never from an unlabeled container, and sent home with the patient. Long-term care is the opposite case, where resident-owned medication is routine and Part 7 governs. The failure mode in both settings is the same, the abandoned bag in a drawer, which is unlabeled stock with a patient's name on it and no owner, and the Phase 3 walk treats it exactly that way.

3h · Hazardous drug handling, short of compounding

Compounding is out of this document's scope, and Appendix B says why. Handling is not. A facility whose formulary carries hazardous drugs, and the facility's own list, built from the national hazardous list cross-filtered to what is actually stocked, is the first artifact, handles them as a category:

- Storage segregated and labeled as hazardous, receipt handled with gloves and inspection for damage
- A spill kit present, in date, and findable by the staff on shift, which the visit tests by asking, not by looking
- Personal protective equipment appropriate to administration-level handling defined in policy, with the line to compounding-level activity drawn explicitly and not crossed
- The waste stream for hazardous items separate from ordinary pharmaceutical waste, per the facility's waste vendor arrangements
- A spill or exposure is an incident with the same discipline as any other: reported at once, documented factually, corrective action if the cause was systemic

3i · Room conditions

The refrigerator gets a log and the room it sits in usually gets nothing, which is backwards: most of the formulary lives at room temperature, and most labels specify it.

- The medication room and every ambient storage location holds controlled room temperature per the labeling, commonly stated as 20 to 25 degrees Celsius with brief excursions permitted between 15 and 30. Confirm against the products actually stocked rather than a number carried from another building.
- Humidity is monitored where the facility's policy or its accreditor requires it, and where cartons and paper labels live, because humidity damage shows up as unreadable lots long before it shows up as a potency question.
- Recording is by the same rule as the refrigerator: a reading exists for every day the building operated, and out of range carries its response at the time.
- Heat sources and light matter. Stock stored against an exterior wall, above a sterilizer, in a window's afternoon sun, or in a closet that shares a wall with mechanical equipment will drift, and the drift is invisible without a thermometer in that specific place.

Where it fails: the room with no thermometer at all; the log that starts the week the surveyor is expected; and the storage decision made because a shelf was empty rather than because the conditions were right.

3j · Fluids, irrigation, and warming cabinets

Intravenous fluids and irrigation solutions are drugs, and they are the most commonly overlooked drugs in an ASC because they arrive by the case and live on a rack.

- They carry lot numbers and expiration dates, they belong on the expiration sweep, and they are inspected for particulates, leaks, and cloudiness on the same walk as everything else.
- Warming cabinets are the finding that surprises facilities. Fluids may be warmed only per the manufacturer's labeling, which sets both the maximum temperature and the maximum duration, and blankets and fluids frequently have different limits, which is why a single cabinet holding both at one setting is a finding waiting to happen. The cabinet has a temperature record like any other controlled-condition location, and warmed fluids carry the date placed in and the discard date out.

- Irrigation solutions used in the sterile field are handled as sterile products: single patient, no topping off, no decanting into an unlabeled basin that then travels.
- Where the facility mixes anything into a bag at the point of care, that is preparation and 3d's immediate-use limits govern, not the fluid's own labeling.

Ask rather than assume here. The warming cabinet's settings are usually owned by nursing or central sterile, not by anyone who thinks of themselves as handling medications, so the question is who sets it, who checks it, and against which manufacturer's document.

3k · Recalls, withdrawals, and shortages

Both are supply events with a clock, and both usually fall to the pharmacist, because few others in the building are watching the feeds.

A recall, step by step:

1. Receive and date it. Recall notices reach facilities by several paths, wholesaler notice, manufacturer letter, FDA feed, and the first duty is that one person owns receipt so a notice does not arrive at the front desk and die there.
2. Check it against this formulary and this stock. Class, product, lot numbers, expiration dates, and every location including trays, kits, carts, and the anesthesia supply, not just the shelf.
3. Quarantine anything matched, physically separated and labeled do not use, the moment it is found.
4. Answer the patient question. If the product was used before the notice arrived, the facility decides on notification with the medical director and its own counsel; the pharmacist supplies the facts, what was used, on which dates, from which lot, and does not make the notification decision alone.
5. Follow the notice's own instructions for return or destruction, and keep the paperwork, because the reconciliation between what was quarantined and what left the building is the record that closes the event.
6. Document the whole event as a finding-class record with an owner and a closure date, and report it into the QAPI feed if it revealed a process gap rather than merely a bad lot.

A shortage, step by step:

1. Identify exposure early: which shortage products are on this formulary, in what quantity, and how many case-days of supply remain.
2. Take the question to the people who decide clinical substitution, the medical director and anesthesia, with the alternatives, their differences in concentration and presentation, and the safety implications of each. A pharmacist recommends; the facility decides.
3. Manage the supply deliberately: conservation, par adjustment, alternative sourcing through the wholesaler, and a written note of what was decided, because a substitution nobody documented becomes a look-alike error six weeks later.
4. Update the affected artifacts. A concentration change ripples into the formulary record, the look-alike and high-alert lists from 6e, the crash cart and tray contents lists, and staff education, and a shortage response that stops at procurement leaves those four undone.

5. Close the loop when supply returns, because the temporary product that quietly became permanent is its own finding.

In TOM MMS a recall check runs against the formulary and the location records rather than against memory, quarantine is a recorded state instead of a taped note, and the substitution's ripple into contents lists and warnings is visible where the ripple has to land.

3l · When the center does pediatric cases

Pediatric practice changes the medication risk profile more than most ASC formularies acknowledge, and the safeguards belong in the record before the first small patient, not after the first near miss.

- Dosing is weight-based, so a current weight in kilograms, recorded in kilograms only, is the safety control. Pounds anywhere in the medication path invites a tenfold error.
- Concentrations are standardized and limited. The fewer available concentrations of a high-risk drug, the fewer ways to be wrong, and the pediatric and adult presentations of the same drug are separated physically and on the look-alike list in 6e.
- Emergency dosing references sized to this facility's population are present where a code would happen, current, and legible under pressure, including reversal agents.
- Any dilution performed at the point of care is preparation under 3d's immediate-use limits, labeled fully, and never carried between patients.
- The tray and cart contents lists reflect pediatric needs specifically, because an adult-sized emergency cart in a center that anesthetizes children is a finding with clinical weight behind it.

3m · Paralyzing agents

Neuromuscular blockers are the clearest case in this document of a drug whose danger is entirely about selection rather than about dose. Given to a patient who is ventilated, they do their job. Given to a patient who is not, because someone reached for the wrong vial, they cause respiratory arrest. The published error reports are consistent about the mechanism: the harm almost always comes from accidental administration when a different drug was intended, not from misuse of the drug itself.

This matters here because the safeguards are almost entirely storage, labeling, and segregation, which is to say they are pharmacy's work and they are auditable on a visit. The national medication-safety best practice set has carried safe storage of these agents as a named item for years, and it is addressed to surgery centers as well as hospitals.

What the visit verifies.

- **Segregated storage, not shelf-adjacent.** The agents are physically separated from other stock rather than sitting beside look-alike vials. Where they are kept as floor stock, the recommended pattern is a distinct sealed container assembled by pharmacy rather than loose vials in a drawer, and the same discipline applies in refrigerated and non-refrigerated locations.
- **Auxiliary warning labels, applied by pharmacy.** The recommended wording warns that the product is a paralyzing agent and causes respiratory arrest, and it goes on the vial, on any prepared syringe, and on the storage container. Manufacturers were asked to strengthen carton and container labeling, so newer stock may already carry it, and the visit checks the stock actually present rather

than assuming a generation of packaging.

- **The labels do not obscure the drug name.** An auxiliary label that covers the identity it is protecting has made the problem worse.
- **Availability limited to where ventilation is possible.** Storage in areas where a paralyzed patient could not be ventilated and monitored is the finding that matters most, and it is worth walking rather than asking.
- **Where an automated cabinet holds them**, per 2j, the recommended controls are an acknowledgment before removal and a search that requires enough characters that a wrong-drug selection cannot happen on two or three letters.
- **Look-alike separation applied specifically.** These belong on the facility's 6e list by name, with their physical separation stated beside the pair, because the reported errors repeatedly involve a vial that resembled something benign.

Where it fails: the center whose paralytic sits in the same bin as a vasopressor because both are small vials in the anesthesia workspace; auxiliary labels applied to the box but not to the vials that leave it; and a facility that added these agents when it added a service line and never revisited where they live.

In TOM MMS these carry their high-alert flag from the formulary, so the warning appears at the moment of the pull rather than only on a bin somewhere. The physical segregation is not something software can do, and this element is mostly a walking audit.

3n · The equipment, and the room it sits in

Every temperature record in this document assumes the equipment producing it is capable and the instrument reading it is accurate. Neither is safe to assume, and both are things a pharmacist can advise on that nobody else in the building will.

The unit. Purpose-built pharmaceutical-grade refrigeration is the standard to advise toward, and a dormitory-style combination refrigerator-freezer is the one to advise against by name. The problem with the latter is not that it fails, it is that it cycles: a single compartment with a cooling plate produces cold spots that can freeze product while the display reads in range. Where a facility already owns one, say so plainly, put the risk in writing, and treat it as a capital finding with a date rather than a paragraph nobody acts on. A separate refrigerator and a separate freezer beat a combination unit.

The instrument. What the record needs is the temperature of the product, not the temperature of the air, which is why a probe in a buffered solution is the standard rather than a bare sensor or a household thermometer. A device that records continuously and holds minimum and maximum values is what makes 3e's monthly curve possible at all; a dial thermometer read once a day tells you almost nothing about the night.

Calibration is the control most facilities have never heard of. A monitoring device drifts, and an uncalibrated instrument produces a record that looks perfect and means nothing. Devices should carry a current certificate of calibration traceable to a recognised standard, and be recalibrated on the interval the manufacturer or the facility's own policy states. The visit checks that the certificate exists, that it is current, and that it names the device actually installed rather than a predecessor.

The room around the unit. Placement away from heat sources and direct sun. Clearance for air circulation behind and around it. A dedicated outlet, because a shared circuit is how a unit gets unplugged for a floor buffer. Stock kept off the door and out of the drawer at the bottom, both of which cycle. And enough space that the unit is not packed so tightly that air cannot move, which is the most common physical cause of an excursion in an otherwise adequate unit.

Where it fails: the dormitory unit bought at opening because it fit the alcove; a calibration certificate for a device that was replaced two years ago; the unit sharing an outlet with a coffee maker; and a refrigerator so full that the reading at the probe has nothing to do with the reading at the back.

The advice to give an administrator. These are cheap decisions made once and lived with for a decade, and the cost of getting them wrong is measured in discarded stock and an excursion nobody can explain. Section 8.10 carries the same logic for security hardware, and the two conversations are usually best had together.

> PROGRAM **Temperature Integrity** · Owner: the Pharmacy Lead records; the pharmacist reads the curve and owns the response standard · Cycle: readings each operating day, the deep reconciliation monthly, calibration on the interval the device requires · Artifacts: the temperature log, the excursion record with its corrective action, and the calibration certificate · Measure: excursions per readings taken, and the share of excursions closed with a documented action

Phase 3 is complete when every named location has been examined against the six questions, refrigeration has been reviewed including excursion handling, and beyond-use practice has been checked as a practice rather than as a snapshot, and the month’s deep reconciliation is on record.

Phase 4 · Emergency equipment

Purpose. Confirm that the equipment used in the worst minutes this facility will ever have is complete, sealed, current, and reachable.

Everything in this phase is low frequency and high consequence. That combination is why it degrades: nothing goes wrong for years, so nobody notices when the checks get thinner.

The federal footing. The Medicare Condition for Coverage at 42 CFR 416.44(d) requires the ASC's medical staff and governing body to specify by policy the types of emergency equipment required in the operating room, and requires that equipment to be immediately available for use during emergencies, appropriate for the facility's patient population, and maintained by appropriate personnel.

Three review questions follow directly from that wording, and they are not the questions most checklists ask.

Is there a policy that specifies the equipment, adopted by medical staff and the governing body? Not a contents list taped to the cart. A policy.

Is it appropriate for this patient population? A contents list inherited from another center is a weak answer to a rule that asks about this one.

Is it immediately available? That is a retrievability standard rather than a possession standard. Equipment that exists but is behind a locked door, blocked, or four minutes away does not meet it. Time the retrieval rather than assuming it.

4a · Crash cart

- Seal present, seal number recorded, seal intact
- The daily or per-policy check log complete for the interval since your last visit, with no unexplained gaps
- Contents verified against the facility's current list, and the list itself current rather than the version the cart shipped with
- Nothing expired, including the items nobody thinks of as medication
- Defibrillator status confirmed, pads in date, battery charged
- Oxygen and suction present and functional
- Cart physically reachable, not blocked, not behind a locked door nobody on shift has a key to

On broken seals. Confirm the facility's policy states what a broken seal obligates, and that the log shows it happened when a seal was recorded broken. A cart with a broken seal and no full internal check is an unverified cart being treated as a verified one.

4b · Malignant hyperthermia cart

The cart least often opened and the one where a gap matters most.

MHAUS recommends that every location where general anesthetics are administered keep a full treatment supply of dantrolene immediately available at all times. For the conventional 20 mg formulation that has

long meant 36 vials, 720 mg total. Newer concentrated formulations deliver a comparable total dose in far fewer vials.

Check the total dose against the formulation actually stocked, and check the facility's policy against both. A center stocking a concentrated product against a written 36-vial policy fails an audit against its own paperwork while being clinically fine. The requirement is a total dose and an availability standard, not a vial count. Do not carry a number forward from another facility.

Also confirm:

- Sterile water for reconstitution, preservative-free, in sufficient volume
- Syringes and needles adequate to reconstitute the entire supply under time pressure, by people whose hands are shaking
- Cooling supplies per current guidance
- Adjunct medications per current guidance, in date
- A current MHAUS treatment poster, where the team can actually see it from where they would be standing
- The MHAUS hotline number, posted and legible

And ask when it was last opened in a drill. A complete cart that has never been rehearsed is inventory, not readiness. Surveyors increasingly ask not whether the dantrolene is present but how staff are guided during an event, and that question is not answered by a cart.

4c · Anesthesia and ANB boxes

Sealed and logged like the carts. Contents against the current list. Every box assigned to a named location, and every named location actually holding the box assigned to it.

4d · The exchange model, and the drill

The exchange model is the hospital's answer to cart rot, imported. Where a pharmacy partner supports it, emergency trays are standardized, pharmacy-sealed units: a tray that is opened, used from, or approaching its first expiration exchanges whole for a sealed replacement, and the opened tray goes back to the pharmacy whole, regardless of what was used. Restocking an opened tray in place, item by item from the shelf, is where crash carts quietly diverge from their contents lists. Where no partner exists, the after-use discipline stands in: a full internal check by two people against the current contents list before the cart reseals, recorded on the reseal form. Either way, breakaway seals, and a seal log with no gaps.

The check and the drill are different proofs. The seal check proves nobody entered the cart. The drill proves the team can. For malignant hyperthermia in particular, the periodic verification opens the cart: the dantrolene count verified against 4b's quantity standard, in date, with its reconstitution supplies physically present, at the interval facility policy sets, not just the seal glanced at daily. And the drill question from this phase's close has follow-ups: the date, the scenario, who mixed, and the observed time to first dose. A drill in which nobody reconstituted a vial from training stock was a walk-through, and the facility should hear that distinction from you before a surveyor makes it for them.

In TOM MMS the cart check records the seal and the equipment attestations, exchange and reseal events

carry their seal numbers, and the drill's date is a record with an owner rather than a memory.

4e · Local anesthetic rescue

Malignant hyperthermia gets attention because dantrolene is famous. The other antidote-class emergency in an ambulatory center gets much less, and it is more likely in a facility that performs regional blocks, infiltrates large volumes, or uses tumescent technique. The clinical management belongs to anesthesia and to the published professional-society checklist. The procedure around the drug belongs to the pharmacist, and that is what this element audits.

The conversation to convene, which is the pharmacist's job and nobody else's. Anesthesia, the medical director, and the pharmacist decide together what this facility stocks, in what quantity, and where it lives. The quantity question is the one facilities get wrong, because a single bag sized to one dose is not an antidote stock for a large patient. Do not decide it for them and do not guess at it. Put the current published checklist in front of the people who will use it, ask what the worst case in this building looks like, and record the answer they arrive at as the facility's written basis. That record is the artifact. Without it, next year's pharmacist has no way to know whether the stock on the shelf was a decision or an accident.

What the visit then verifies, against that written basis rather than against your own opinion:

- The product is present, in the quantity the facility's own basis states, and in the location that basis names.
- It is in date and on the expiry sweep like any other stock.
- The administration supplies are stored with it rather than nearby, because a kit that sends someone looking for tubing has spent the minutes that mattered.
- The current version of the checklist is posted with it. The publisher permits free reproduction for clinical and educational use, so confirm the version rather than assuming the posted copy is current.
- Staff can say where it is without looking. Ask, do not inspect.
- The facility's protocol addresses the substitution question directly, because reaching for a lipid-containing anesthetic agent instead is a common assumption and the protocol should settle it rather than leaving it to recall under pressure.

Where it fails: the center that added regional blocks to its case mix and never revisited its emergency stock; the antidote stored in the storeroom rather than where blocks happen; the kit built once at opening against a checklist that has since been revised; and a quantity nobody can explain because the decision was never written down.

In TOM MMS the rescue kit is a location like the crash cart, carrying the same contents list, checks, and expiry dates, which is what stops it becoming the one kit nobody opens.

> PROGRAM **Emergency Readiness** · Owner: the Pharmacy Lead checks; the medical director owns the drills · Cycle: seal checks daily, restock immediately after any use, contents verified against the list on the facility's stated interval, drills at least annually · Artifacts: the cart check record, the contents lists, the seal log, and the drill record · Measure: seal record completeness, and the date of the last drill in which a vial was actually reconstituted

Phase 4 is complete when every cart and box has been examined against its current contents list, seals and logs are verified for the full interval, the antidote stocks are sized to a real patient rather than to a single dose, and you have asked about the last drill and heard a date and a mixed vial in the answer.

Phase 5 · Ordering and returns

Purpose. Account for how controlled substances enter the building and how they leave it other than into a patient.

Everything in Phase 2 assumes the perpetual inventory's inputs and outputs are themselves accurate. This phase is where that assumption gets tested.

5a · Ordering records

DEA Form 222 or CSOS records, reviewed for completeness and sequence.

- Forms accounted for in sequence, including voided ones. A missing form number is a finding on its own.
- Each order matched to what was actually received, and any partial fill documented
- Copies retained as required and retrievable at the registered location
- For CSOS, the digital certificate is current and belongs to someone still employed here

A certificate tied to a departed employee is a live problem, and it is invisible until an order needs placing.

5b · Receiving

Invoices matched to what physically arrived and to what was entered into the perpetual inventory. Three records that should agree and frequently do not.

Look for: quantity received versus quantity invoiced versus quantity logged, delays between arrival and entry, and anything received but never entered.

5c · Returns, waste, and destruction

- Waste records complete, with witness where required
- Returns to a reverse distributor documented, with the paperwork retained
- Destruction records reviewed, with particular attention to anything sitting in draft or unresolved

An open destruction record is an open regulatory record and it ages visibly. A draft from months ago is a finding whose severity increases with time and whose existence is difficult to explain to an investigator, because the obvious question is what happened to the drug in the meantime.

5d · Performing the functions, not just auditing them

Everything above is the audit view. A pharmacist standing up a program, or covering for a facility that has never done these correctly, also needs to run the machine. The four functions, as performed:

Placing a Schedule II order.

1. Confirm who may sign. Only the registrant, or a person holding a signed power of attorney from the registrant, executes Form 222 or holds the CSOS signing certificate. Keep the power of attorney with the ordering records; it is the first thing an investigator asks for when a signature does not match the registration.

2. On paper: complete the 222 legibly, one item per line, no unexplained alterations; a spoiled form is voided and retained, never discarded, because the sequence must account for every serial number.
3. On CSOS: the order is signed with the certificate holder's own credential; a certificate belonging to someone who left is deactivated the day they leave, not discovered at the next order.
4. Record what was ordered in the receiving expectation, so 5b's three-way match has its first leg before the truck arrives.

Receiving against the order. One sitting, three records: the order, the invoice, the shelf. Count what physically arrived, line by line against the invoice, then both against the order; document partial fills on the order record itself; enter the received quantities into the perpetual inventory the same day. A discrepancy at the dock is a phone call; the same discrepancy discovered at reconciliation is a variance investigation.

Returning and destroying.

1. Route expired and unusable controlled stock to a reverse distributor as the default path: sequester it, marked and separate, until pickup; document the transfer on the distributor's paperwork and Form C-26; retain everything.
2. On-site destruction by a registrant is the exception, and it carries its own federal machinery: the method must render the substance non-retrievable, two employees witness, and DEA Form 41 is the record of what was destroyed, by whom, how, and when. The 41 lives in the facility's records; it is not routinely mailed anywhere.
3. Either path, the perpetual inventory is decremented when custody changes, and nothing sits in a draft state. 5c's aging rule exists because the gap between "set aside to destroy" and "destroyed" is where drugs disappear.

Reporting theft or significant loss. Two steps, both mandatory, and the second changed in 2023:

1. Within one business day of discovery, notify the local DEA field division office in writing. Discovery starts the clock, not the end of the internal investigation.
2. Within forty-five calendar days, file DEA Form 106 electronically through the Diversion Control Division's secure online application. Paper 106s no longer exist; the DEA stopped accepting them in July

2023. The duty survives recovery of the drug and identification of who took it, and every theft is reportable regardless of quantity. State reporting runs in parallel per the jurisdictional baseline.

Where the instruments live, because this document links rather than reprints, deliberately: the 222 is a serialized instrument issued to the registrant by DEA, and a reproduction is not valid for ordering; the 106 no longer exists on paper at all; and a reprinted government form goes stale the day the agency revises it.

Instrument	What it is	Where it lives
DEA Form 222	Serialized Schedule I and II order form, issued to the registrant	Requisitioned from DEA through the registrant's account; never photocopied for use
CSOS	The electronic 222: certificate-based	Enrollment and certificates through

CSOS	The electronic 222: certificate-based ordering	Enrollment and certificates through DEA's CSOS program
Power of attorney	Authorizes a named person to sign orders for the registrant	Drafted by the facility, signed by the registrant, kept with ordering records
DEA Form 41	Registrant destruction record	Fillable form from the DEA Diversion Control Division site; completed and retained in facility records
DEA Form 106	Theft or significant loss report	Electronic only, through the Diversion Control Division's secure Theft/Loss application
Registration and renewal	The facility's DEA registration lifecycle	DEA Diversion Control Division registration portal; renewal dates on the Phase 6 calendar

In TOM MMS the DEA-222 order tracker carries the sequence and the receiving match, incident reporting routes a suspected theft to the pharmacist the day it is found, and the destruction workflow refuses to let a draft age quietly.

5e · Expired non-controlled stock, returns, and credit

The controlled path in 5c is the one with federal machinery. The much larger volume, ordinary expired and short-dated stock, has its own cycle, and running it is real money the pharmacist returns to the facility.

1. **Find it before it expires.** The ninety-day horizon from Module 9 is the point of the exercise: most wholesalers and returns processors credit short-dated product within a window before expiry and credit nothing after it. Stock pulled at ninety days is often worth money; the same vial found at ninety days past is worth a disposal fee.

Beyond the floor. The rule is only that expired stock must not be available for use. This standard works a ninety-day forward horizon instead, because catching a vial before it expires is a purchasing decision and catching it afterward is a disposal cost. 2. **Pull and segregate.** Anything expired or short-dated comes out of the active location at the moment it is found, into a marked quarantine that is not a shelf people reach into. 3. **Sort by path.** Manufacturer-direct return, wholesaler return, third-party returns processor, or destruction, according to the facility's agreements and each product's eligibility. Hazardous items follow 3h's waste stream instead. 4. **Document the shipment.** What went, in what quantity, on what date, to whom, with the paperwork retained. A return with no record is indistinguishable from stock that disappeared. 5. **Reconcile the credit.** Someone has to check that the credit actually arrived and matches what was sent. This is the step nearly every facility skips, and it is the one that turns the pharmacist's expiration work into a number the administrator can see in Module 8's report.

Beyond the floor. Nothing requires anyone to check that a return was credited. This standard requires it, because a return with no reconciled credit is indistinguishable from stock that left the building unaccounted for, and because it is the step that makes the pharmacist's expiry work visible as money. 6. **Ask why it expired.** A recurring expiry in the same product is a par level problem, not a diligence problem, and fixing the par is worth more than the credit.

> PROGRAM **Expiry and Returns** · Owner: the Pharmacy Lead pulls; the pharmacist verifies and closes the credit loop · Cycle: the ninety-day horizon worked monthly, returns shipped on the facility's cycle, credits reconciled each period · Artifacts: the expiration tracker, the return and destruction records, and the credit reconciliation · Measure: expired stock found per visit, and returned value actually credited as a share of value shipped

Non-returnable and destroyed stock still gets recorded, because the gap between what left the shelf and what left the building is exactly where diversion hides, controlled or not.

In TOM MMS the expiration tracker surfaces the ninety-day horizon by location, and the return record keeps the credit reconciliation attached to the shipment instead of living in an email thread.

5f · Supply chain integrity

Everything on the shelf should be traceable to a legitimate source, and the federal drug supply chain law makes that a records question rather than a matter of trust.

- Purchases come from licensed wholesale distributors or the manufacturer, and the facility can produce evidence of that licensure on request. Verify it at engagement start and on renewal rather than assuming it.
- Transaction information travels with product between trading partners and is retained per the federal requirement. Practically, this is the paperwork the wholesaler provides and the facility keeps, and the test is whether it can be produced for a given lot.
- Suspect or illegitimate product has a defined response: quarantine, notify the trading partner and the FDA per the rule, and do not return it into inventory while the question is open.
- Deals that arrive by cold email offering scarce drugs below market are the classic entry point for diverted or counterfeit product. The rule in this document is simple: unknown sources are not sources.

Phase 5 is complete when ordering records are accounted for in sequence, receiving reconciles against the perpetual inventory, nothing in the destruction path is aging unexplained, the non-controlled return cycle has its shipments and its credits reconciled, and whoever performs 5d's functions can show the authority and the records behind each one.

Phase 6 · Compliance documentation

Purpose. Confirm that the facility's paper describes what the facility actually does, and that events which required a response got one.

The phase most often rushed, and the one that most often holds the finding a surveyor would have found.

6a · Incidents

Every incident since your last visit. For each: was it documented, was it investigated, was there a corrective action, and did anything change.

The question is not whether incidents occurred. A facility reporting zero incidents over a long period is not a safe facility, it is a facility that has stopped reporting, and that is the more serious finding.

Medication errors and adverse reactions carry a specific federal obligation: adverse reactions must be reported to the physician responsible for the patient and documented in the record. Check both halves.

Near misses are incidents. An error caught before it reached the patient is the cheapest learning the facility will ever get, and a reporting culture that captures near misses is the strongest single predictor that the serious events get reported too. Ask to see them. A file with none is not a clean record, it is a quiet one.

6b · Staff training and competency

Who is current, who is not, and who was hired since your last visit.

- New staff trained before they touched medications, not scheduled to be
- Annual refreshers current
- Records retrievable per person rather than per session

Turnover is the signal. A facility with three new nurses since your last visit has three people running the medication routine on inherited habits unless someone trained them.

6c · Policies and procedures

Reviewed for currency against the facility's accreditation body and state board, and reviewed for truth against practice.

A policy that does not describe what the facility does is worse than no policy, because it is a written admission of noncompliance. When you find a gap, determine which side is wrong. Sometimes the practice needs to change. Sometimes the policy was written for a facility this one no longer is.

Confirm the annual review actually happened and is dated, and that the named individual responsible for pharmaceutical services is named in the manual and is the person actually doing it.

6d · Audit trail

Records complete, attributable, and unaltered. Amendments handled as amendments: the original preserved, the correction separate, both signed.

A record that can be altered without a trace is not evidence, and it will be treated that way by

anyone evaluating it later.

6e · The lists the facility owns

Two lists drive half the point-of-care safeguards in this document, and both decay without an owner: the look-alike sound-alike list and the high-alert list. The standard is that the facility maintains its own, built from the national references and then cross-filtered to its actual formulary, because a generic poster of someone else's risks trains staff to stop reading posters.

Where the source material comes from. The Institute for Safe Medication Practices publishes the List of Confused Drug Names, which collects look-alike and sound-alike name pairs and incorporates both the FDA-approved and the ISMP-recommended tall man letters. ISMP also publishes the high-alert medication lists for acute care and for community and ambulatory care. ISMP permits reproduction with attribution for internal use within a healthcare organization, which is exactly the use a facility list makes of it. Confirm the current edition rather than the copy already taped to the wall, because the list is revised and the last revision added more than eighty name pairs.

Building the facility's own list, in four steps.

1. Take the current ISMP list and keep only the pairs where **both** members are on this facility's formulary, or where one is on the formulary and the other is plausibly orderable into the building. A pair the facility cannot stock is noise, and noise is what teaches people to stop looking.
2. Add the pairs the national list will never contain: the confusions specific to this building. Two concentrations of the same drug sitting side by side. A pediatric and an adult presentation in one drawer. Two products that look alike because of the vial rather than the name, which is a real category the name-based lists do not cover at all.
3. For every surviving pair, decide the safeguard and write it down beside the pair. Tall man lettering on the shelf label and in the system. Physical separation, meaning a different shelf or a different bin rather than a divider. An auxiliary label. A forcing check at the point of use for the worst of them.
4. Date it, name its owner, and set the review. The list is a controlled document, not a poster.

Tall man lettering is a decision, not a font. It works by drawing the eye to the part of two names that differs, so it only helps where it is applied consistently in every place the name appears: the shelf label, the bin, the formulary record, the screen at sign-out, and the auxiliary label. Applied in one place and not the others, it teaches staff that the emphasis means nothing.

High-alert is a different question from look-alike. A look-alike pair is about selecting the wrong drug. A high-alert drug is one where selecting the right drug and getting the dose wrong causes serious harm. The safeguards differ accordingly: separation and differentiation for the first, independent double checks and standardized concentrations for the second. A facility that merges the two lists ends up applying the wrong control to both.

The visit verifies four things:

1. **The lists are current.** A review date within the year, and a revision on any formulary change that touches them.
2. **The source edition is current** rather than inherited.

3. **The shelf agrees with the list.** The separations, the auxiliary labels, and the storage decisions the list implies actually exist where the drugs live.
4. **The warnings staff see at the point of care match the lists.** The flag on the screen or the sticker on the bin is the list doing its work rather than a decoration with a different ancestry.

> PROGRAM **Look-Alike and High-Alert** · Owner: the pharmacist proposes; the facility's own structure approves and owns · Cycle: reviewed at least annually and on any formulary change that touches an entry · Artifacts: the two facility lists with a safeguard named beside every entry, the shelf labels, and the point-of-care warnings · Measure: list currency, and the agreement rate between the list and the shelf

Where it fails: the list built once at opening and never revised while the formulary moved underneath it; the national list printed whole and posted, so staff scan past forty pairs the building has never stocked to reach the two it has; tall man lettering in the system but not on the shelf; and a high-alert list with no stated safeguard beside any entry, which is a list of adjectives.

In TOM MMS the formulary carries the flags, which is what makes the sign-out warnings in Topic 1 the list itself doing its job at the moment of the pull rather than a policy somebody read once.

6f · Allergy and medication history documentation

Same-day surgery compresses the medication history into the pre-operative window, which makes its documentation thin in exactly the places that matter.

- Allergies are recorded with the reaction, not just the substance, because "allergic to codeine, nausea" and "allergic to codeine, anaphylaxis" are different clinical facts and only one of them should stop a plan.
- No known allergies is an affirmative entry, not a blank field. A blank is indistinguishable from nobody having asked.
- The allergy record is visible where medications are selected and administered, not only in the chart's front matter, and it agrees with itself across the pre-operative record, the anesthesia record, and the medication administration record.
- Non-drug sensitivities that change medication and material choices, latex being the standing example, are captured in the same place and reach the people who set up the room.
- Home medication information is collected to the extent the procedure requires it, anticoagulants, diabetes agents, and anything with a hold instruction most of all, and the hold instructions given to the patient are documented as given.

The pharmacist audits the documentation and its consistency. Clinical decisions about a specific patient remain the treating team's.

6g · Reporting outward

Some events leave the building, and knowing which is a pharmacist function nobody else in an ASC is positioned to hold.

Event	Where it goes	Nature
Adverse drug reaction	The physician responsible for the patient, per the federal condition, and the facility's own quality record	Mandatory
Suspected product defect, contamination, or device failure	FDA's MedWatch program	Voluntary for the facility, expected practice, and the only way a defect becomes visible nationally
Medication error, for learning	A national error-reporting program such as the ISMP program	Voluntary and confidential
Theft or significant loss of controlled substances	DEA per section 5d, and the state per its own rule	Mandatory, on the two-step clock
Events the state requires reported	The state board or health agency per the jurisdictional baseline in A.3	Mandatory, and state-specific
Recalled product the facility used	Handled per 3k with the medical director and counsel	Facility decision

Voluntary is not optional in spirit. A facility that reports nothing outward learns only from its own mistakes, and the reporting programs exist because the same defect usually appears in several buildings before anyone connects them.

6h · Formulary governance

The formulary is referenced everywhere in this document, by the recall check, the shortage response, the look-alike list, the deep reconciliation, and it is worth almost nothing unless someone owns it.

- **There is an approved list, and it is dated.** A formulary that exists only as whatever the wholesaler shipped is not a formulary, it is a purchase history.
- **Approval belongs to the facility's own structure**, typically the medical staff or a quality committee acting on the medical director's recommendation, with the consultant pharmacist as the technical voice rather than the approver. In settings where the pharmacy class itself requires a committee, freestanding emergency centers being the example in Part 9, the required structure governs.
- **Changes are recorded as changes**, with the date, the reason, and who approved, because the question at survey is not what is stocked but how it came to be stocked.
- **The cycle is at least annual**, and additionally on any of the triggers: a shortage substitution that outlived its emergency, a new procedure or service line, a recall that removed a product, a formulation change, or a safety event pointing at a drug on the list.
- **Additions carry their consequences.** A drug added without checking storage conditions, look-alike risk, waste path, and whether anyone is trained on it is an addition that becomes a finding.

Where it fails: the list nobody has revised since opening; the "formulary" that is a spreadsheet of prices; and the addition made because one surgeon asked and nobody recorded the decision, which is indistinguishable at survey from stock that arrived by accident.

6i · The antimicrobial stewardship program

Prophylactic antibiotics are the most commonly given medication class in a surgery center, and the class most often missing from the pharmacist's review because it feels like a surgical decision. The selection for a given patient is a surgical decision and stays one. The program around it is a pharmacist's work, and it is one of the clearest opportunities in this document to be genuinely useful rather than merely compliant.

Beyond the floor. Hospitals have been required to run antimicrobial stewardship programs since the Medicare conditions of participation were amended, and nursing homes have their own framework. Ambulatory surgery centers were left out: the major accreditors excluded ASCs from the medication management standards that carry stewardship, so most centers have no obligation here at all. That is exactly why a pharmacist who brings one is bringing something the facility cannot get from its accreditation consultant, and why this element is a service rather than an inspection.

The framework to build on. The national outpatient framework has four elements, and they translate to an ambulatory center without much adaptation: commitment, action on policy and practice, tracking and reporting, and education. Use that structure rather than inventing one, because a facility that ever comes under a requirement will be measured against it.

Element one, commitment. A written statement that the facility is committed to appropriate antimicrobial use, and a named person accountable for it. In an ASC that person is usually the medical director with the consultant pharmacist as the technical support. Written and named, or the other three elements have nowhere to attach.

Element two, action. The facility has a written prophylaxis protocol for the procedures it actually performs, derived from the current national surgical prophylaxis guideline rather than from habit or from another facility's copy, approved through the facility's own structure per 6h, and dated. The pharmacist's role is to bring the current guideline, convene the review, and make sure the protocol answers the questions the guideline raises: which agent for which procedure, what happens when the patient's weight is outside the standard assumption, what happens in a long case, when prophylaxis stops, and what to do with a documented allergy. The pharmacist does not decide those answers. The pharmacist makes sure the facility has decided them, in writing, against a current source.

Element three, tracking and reporting. This is the part that makes the program real, and it is a records audit rather than a clinical judgment. Take a sample of cases and compare what happened against the facility's own protocol: was the agent the one the protocol names, was the dose the one the protocol states, and was the timing within the window the protocol sets. Report the match rate as a number with its denominator, per period, to the quality committee. Three things about this audit matter:

- **You are measuring against their protocol, not against your preference.** If the protocol is wrong, that is an element-two finding and it gets fixed there. Conflating the two turns an audit into an argument.
- **Timing is usually the first finding, and it is usually a records finding.** Many facilities cannot demonstrate the timing measure at all because the administration time is not captured in a retrievable way. That is a documentation fix, not a clinical one, and it is the pharmacist's to solve.
- **The match rate is a ready-made QAPI indicator.** It belongs in the 6.6 set for any facility that wants it, and it is one of the few medication measures an administrator already recognises, because

it sits inside the infection prevention program they are already reporting on.

> **PROGRAM** **Antimicrobial Stewardship** · Owner: the medical director is accountable; the pharmacist is the technical support · Cycle: protocol reviewed at least annually, practice audited each period, results to the quality committee · Artifacts: the written commitment, the facility protocol, and the audit with its denominator · Measure: the rate at which practice matches the facility's own protocol

Element four, education. Short, specific, and aimed at the people who execute rather than at the people who prescribe: what the protocol says, where it lives, what to do when the case runs long, and how the timing gets recorded. The prescriber-facing half belongs to the medical director, and the pharmacist supports it with the data from element three rather than leading it.

Where it fails: a protocol inherited from a facility with a different case mix; a timing standard nobody can evidence; no named owner, so the protocol ages without anyone noticing; an audit that reports impressions rather than a rate with a denominator; and a pharmacist who turns the audit into a clinical disagreement with a surgeon, which ends the program.

The boundary, stated plainly. The pharmacist builds and runs the program, audits the process, and reports the pattern. Antimicrobial selection, dosing, and duration for an individual patient are the treating team's decisions, made against the facility's own approved protocol. Section 5.9 governs, and it governs here more often than anywhere else in this part.

Phase 6 is complete when incidents are closed or open with owners, training currency is established per person, the manual has been checked against practice rather than against itself, and the audit trail has been examined for gaps.

Phase 7 · Facility walkthrough

Purpose. See the building without a checklist in front of you.

Phases 2 through 6 tell you where to look. Phase 7 is where you notice what nobody thought to ask about. It is deliberately unstructured, and it should stay that way, because the moment it becomes a list it stops doing its job.

Walk the medication path the way a drug moves: arrival, storage, preparation, administration, and waste. Walk it in that order and notice where it is interrupted.

Figure 3 · The medication path

```
ARRIVAL > STORAGE > PREPARATION > ADMINISTRATION > WASTE
```

Walk it in this order. Notice where it is interrupted, because the interruption is where the finding lives.

[Figure for design render. The text version is the spec.]

Things that turn up in this phase and almost never in the others:

- A medication on a counter with no one near it
- A drawer that does not close, so it is left open
- A sharps or waste container in a place the public can reach
- A refrigerator with a note taped to it explaining a workaround
- A cabinet propped, wedged, or with the latch taped
- Hazardous waste in the wrong stream
- A workaround someone invented because the correct process is impractical

That last one is the most valuable finding in this phase. A workaround is evidence that a policy does not fit the work. Write down the workaround, not just the violation, because the workaround tells you what to fix.

Ask a nurse to show you something rather than tell you. Watching someone log a waste is worth more than reading a month of waste records.

Watch the preparation, not just the room. Where the walkthrough coincides with medications being drawn up, observe the technique itself rather than the counter it happens on: hands and gloves, the septum swabbed and allowed to dry, a new needle and syringe for every entry into a vial, the syringe labeled at the moment it is drawn, nothing prepared in advance of the patient beyond what 3d permits, and nothing left uncapped on a field while attention moves elsewhere. Observation is the practical way this element gets verified, because records rarely capture technique. Where the observation raises a concern, it is coached to the Lead and the DON as a practice pattern, never corrected across a sterile field mid-case.

Phase 7 is complete when you have walked the full medication path and recorded what you saw, including the things that were fine.

Phase 8 · Wrap-up and reporting

Purpose. Make sure the facility knows what you found before you leave, and that the record is complete while you still remember it.

8a · Summarize

Organize findings by severity. Critical first, and critical findings should already have been raised when you found them rather than saved for the debrief.

8b · Debrief the director or DON in person

The first time leadership sees a finding should be from you, not from a document. A finding delivered in writing without warning reads as an accusation. The same finding delivered in conversation reads as help.

Structure that works:

1. What is going well. Say it first and mean it, and be specific enough that it is clearly not a formality.
2. What needs attention, most serious first, with the rule or standard behind it.
3. What you agreed: owner and date for each. Agreed, not assigned.
4. What is coming: expirations, survey window, anything due before next visit.

Get the dates agreed out loud. A date the facility did not agree to is a date you invented, and it will pass.

8c · Schedule the next visit

Before you leave. A visit not scheduled is a visit that slips, and cadence is the one thing in this program that cannot be recovered retroactively.

8d · Sign and submit

Against the close conditions in section 1.7. Within 24 hours, and sooner if you can. Anything not completed is recorded as not completed, with the reason.

Phase 8 is complete when leadership has heard the findings from you, every finding has an owner and an agreed date, the next visit is scheduled, and the record is submitted.

1.6 What a finding must contain

A finding that cannot be acted on is a note. To qualify as a finding it carries all five:

1. **What was observed.** Factual, specific, and dated. Not “temperature logs incomplete” but “refrigerator temperature log missing readings on 4 and 5 August.”
2. **Why it matters.** The rule, standard, or facility policy implicated. Cite the source. If the source is professional judgment rather than a rule, say so.
3. **Severity.** Critical, important, or informational. See below.
4. **An owner.** A named role or person at the facility, not “staff.”
5. **A due date.** Proportional to severity.

Severity definitions

Critical. Patient safety exposure, a controlled substance discrepancy, or a condition that would produce a citation on the day observed. Communicated before you leave the building, not in the report. Due immediately or on a date the facility commits to before you leave.

Important. A gap that will produce a citation if it persists, or a control that exists but is not being followed. Due before the next visit.

Informational. An improvement opportunity, a coming deadline, or a practice that is compliant but fragile. No due date required, but it is tracked and it appears in the quarterly review.

On severity discipline. Inflating severity trains a facility to ignore you. Deflating it is worse. When genuinely uncertain, rank it up and say in the finding why you were uncertain. A reviewer can downgrade a documented judgment. Nobody can recover a finding that was never written.

1.7 The close

A visit is not complete until all of the following are true. This is the checklist a pharmacist runs before signing.

- Every applicable phase is marked complete, N/A, or issue found. No phase is left pending.
- Every issue-found step has a corresponding action item or CAPA with an owner and a due date.
- The controlled substance reconciliation is saved, and any variance is documented and under investigation.
- Temperature excursions and cart check gaps have documented corrective actions.
- The education log records any session delivered, with attendees.
- A narrative summary of two to five sentences is attached: what the facility is doing well, what needs attention, what is coming.
- The visit is signed with a real signature and a real time out.

Submit within 24 hours. Sooner is better, and same day is ideal, because a report written from memory three days later is a reconstruction rather than a record. Twenty-four hours is the outer edge, and it is set there deliberately: visits run late, life happens, and a rule that cannot be met in a normal week is a rule people quietly stop meeting.

Partial visits are allowed and are normal. A center is slammed. A case runs long and the room you needed is occupied. The DON is dealing with something real. You have somewhere you have to be. All of that is ordinary, and none of it is a failure.

What matters is not that every visit is complete. It is that the record says what actually happened.

- Record the phase as skipped, with the reason, in one line.
- Say when it will be picked up, usually the next visit.
- If something skipped is high-consequence, say so and agree a plan before you leave. A controlled substance reconciliation deferred twice in a row is worth a conversation, not a note.

The only thing that cannot happen is signing for work not done. Skipped and recorded is a working program. Skipped and marked complete is the failure this whole standard exists to prevent, and it is the one thing here with no flexibility in it.

Everything else in this section is a target to aim at, not a test to pass.

1.8 How the standard is enforced

This is the part most programs leave to goodwill.

The TOM standard is executed inside TOM MMS, which enforces it structurally rather than by reminder. The phases are the application’s phases. A step cannot be silently skipped, because its status is recorded. A finding cannot exist without an owner, because the record requires one. A signature is bound to the signer and stamped when it happens. The visit record is visible to the facility in their own system, not in a portal we control, which means the evidence belongs to them.

A pharmacist may run this standard on paper. It works, and it is better than no standard. But every control above then depends on the pharmacist remembering, and the entire reason this document exists is that memory is where consistency goes to die.

The application’s own how-to lives outside this document, in four role operating manuals: Pharmacist, Nurse, Admin, and Auditor. They ship in the facility onboarding packet and inside the application, they are revised with each significant release, and this standard deliberately does not duplicate them, because a standard versioned annually should not carry instructions for software that ships weekly.

PART TWO

Training the Pharmacist

PART 2 · TRAINING THE PHARMACIST

What this part is for. A standard is only as good as the person carrying it into the building. This part prepares that person: what they must know before a first solo visit, what they are expected to be able to do rather than merely to have attended, and how the training is evidenced.

Nine modules, and the order matters. The setting comes first because a pharmacist who does not recognise the building gives advice that cannot be followed. The regulatory spine comes second because everything after it is a determination. The rest build outward from the visit to the relationship, the numbers, and the practice of getting ahead of problems.

Inside: the two audiences, what this training is and is not, pharmacist preparation and its prerequisites, Modules 1 through 9, and the records retained for both curricula.

2.1 Two audiences, one standard

A pharmacy program has two operators and they are prepared differently.

The pharmacist visits on the facility’s cadence, exercises judgment, and signs. Preparation here is about standardization: a pharmacist arriving from hospital or retail practice is a competent pharmacist who has never run an ASC visit, and the gap is procedural rather than clinical.

The facility Pharmacy Lead runs the daily routine between visits. This is almost always a nurse. In most surgery centers this person was never trained for the job, inherited it from whoever held it before, and learned it nurse to nurse. Preparation here is about capability: giving the person who actually operates the medication system the knowledge to operate it deliberately.

The second audience is the one most programs neglect, and it is the one that determines whether findings recur. A pharmacist can close the same finding four visits running. A prepared Pharmacy Lead prevents it.

2.2 What this training is, and is not

This is an operating procedure, not a certification. Nothing here carries continuing education credit, board recognition, or legal standing, and TOM is not an ACPE-accredited provider. Where CE credit matters to you, an ACPE provider is the right place to get it.

Inside TOM, completing this training is how a pharmacist becomes ready to work under the TOM standard. Outside TOM, it is a curriculum you are welcome to download and run in your own practice however you see fit, with or without attribution and with or without us. That is the point of publishing it.

2.3 Pharmacist preparation

Before starting

For a pharmacist working under TOM, five things are in place first. For a pharmacist running this independently, the first two are yours to determine and the rest are still worth having.

#	Item
1	Active, unencumbered pharmacist license in the state of practice
2	Professional liability coverage appropriate to consultant practice
3	Executed agreement and confidentiality terms with the engaging entity
4	Executed Business Associate Agreement with each facility
5	HIPAA workforce training, dated

Item 5 is not a formality. Texas HB 300 expands covered entity to any person or business that uses or discloses PHI and requires training within 90 days of hire, with updated training after a material change in the law affecting your duties, no later than one year after the change. A consultant pharmacist touching facility records is squarely inside it. Confirm the equivalent in your own state.

PART 2 · TRAINING THE PHARMACIST

The Nine Modules

Module 1 · The ASC setting

Who needs this. Every pharmacist whose background is hospital, retail, or long-term care, which is nearly everyone. The gap is procedural, not clinical.

The problem this module solves. A competent pharmacist applies a correct standard from the wrong setting and produces findings that are technically defensible and practically useless. A retail pharmacist looks for dispensing records that do not exist. A hospital pharmacist expects a pharmacy department, a 24-hour presence, and a technician workforce, and finds a nurse with a key.

What is actually different

There is no dispensing. Medications are stored, prepared, and administered on site by clinical staff. Nothing is labeled for a patient to take home in the usual sense. The regulatory questions are about storage, accountability, and administration rather than about a prescription.

There is no pharmacist on site. This is the defining fact of the setting. Every control you would delegate to a pharmacy department is delegated to nursing, and nursing was not trained for it. Design every recommendation for the person who will actually execute it.

Anesthesia is a parallel medication system. The anesthesia professional draws, labels, administers, and wastes largely independently of anything nursing does, often from a cart they treat as personal. This is where controlled substance volume concentrates and where the record is thinnest.

Immediate-use preparation is not compounding. Understand the distinction and its limits, because a facility that has drifted past immediate-use into something else has a compliance problem it does not know it has.

Volume is high and inventory is small. A center can move significant fentanyl through a cabinet that holds very little at any moment. That ratio is what makes diversion both easier to accomplish and easier to detect, if anyone is looking.

The building empties. Nights, weekends, and holidays with nobody there. Access control and after-hours security matter more than in a facility that never closes.

Turnover is constant and often per-diem. The person who ran the medication routine last quarter may be gone, and the knowledge left with them.

How you know it landed. The pharmacist can explain, without prompting, why a control that works in a hospital fails in an ASC, and can name what they would substitute. Handout D-1 is the setting on one page.

Module 2 · The regulatory spine

Who needs this. Everyone, and it is state-specific, so part of it is homework rather than instruction.

Federal, ASC

The Medicare Condition for Coverage at 42 CFR 416.48 requires an ASC to provide drugs and biologicals safely and effectively, in accordance with accepted professional practice, and under the direction of a designated individual responsible for pharmaceutical services. Adverse reactions are reported to the responsible physician and documented. Blood and blood products are administered only by physicians or registered nurses. Oral orders must be followed by a written order signed by the prescribing physician.

Three consequences the pharmacist must be able to state:

1. A facility that cannot name the individual responsible for pharmaceutical services has a finding before you open a cabinet.
2. “Accepted professional practice” is the phrase that gives your professional judgment regulatory weight. The rule does not enumerate practices, which means your reasoning matters and must be written down.
3. Verbal orders are a documentation obligation with a federal source.

Federal, controlled substances

21 CFR Part 1304 for records and inventories, including the biennial requirement, the retention period, and the exact-count rule for Schedule II. Form 222 and CSOS for ordering. Reporting obligations for loss and theft.

Know what is not required. There is no federal reconciliation requirement. When you recommend reconciliation, you are recommending professional practice and possibly a state rule, and you should say which. A pharmacist who cites a federal rule that does not exist loses the room permanently.

Accreditation

AAAHC, The Joint Commission, QUAD A, ACHC, plus CMS or the state directly.

The module does not teach the manuals. It teaches the pharmacist to determine which body surveys the facility they are in, obtain that body’s current standards, and work against them rather than against a generic memory of accreditation.

State

The most variable layer and the one that produces the most avoidable errors.

This module does not teach any state’s rules. It teaches the method in Appendix A.3: the pharmacist establishes a written jurisdictional baseline for their own state, answering sixteen defined questions with a citation and a date beside each answer, and refreshes it annually.

Work through Appendix A.3 in full during this module, and produce the baseline as the module’s output rather than as homework. Handout D-2 is the worksheet for it. A pharmacist who leaves this module without a written baseline will not build one later.

The two rules that matter most, both from A.3.4. Where federal, state, accreditation and facility policy all speak, the strictest governs. Where the state is silent, silence is not permission, and a written question to the board beats an assumption.

How you know it landed. The pharmacist hands you a completed, dated, sourced baseline for their state, and can say where they would start for a state they have never worked in.

Module 3 · The visit standard

Who needs this. Everyone, and it is the core of the training.

Content. Part 1 of this document, phase by phase, with the purpose of each phase taught before its steps. A pharmacist who knows the steps but not the purpose will execute the phase and miss the point of it.

Emphasis, in order:

Why the order is the order. Controlled substances come before storage because a variance changes what you look for everywhere else. Wrap-up comes last because a debrief on incomplete information is worse than no debrief.

The completion conditions. Each phase has one. Learn them as the actual test of whether the phase is done, rather than the time estimate.

Severity assignment. The hardest judgment in the standard and the one most prone to drift. Practice on written examples until calibration is visible. Handout D-3 is the case set.

The close. Section 1.7, memorized. It is short and it is the last defense against a visit that was rushed. Handout D-4 puts it in a pocket.

Taught by comparison, not by lecture. Give the trainee three real findings and have them assign severity, then discuss the disagreements. The disagreements are the module.

How to run the module. Walk Part 1 together with a printed copy, phase by phase, purpose before steps. Then the trainee closes the document and writes the eight completion conditions from memory. The misses are the syllabus, and they are usually the same three.

The time-collapse drill. Give the trainee a visit that has lost half its time: a case ran long, the room is occupied, forty minutes remain. Have them say out loud what gets cut, what gets shortened, and what never moves. The answers teach priorities better than any lecture. Phase 2 is never cut. A variance freezes everything behind it. The walkthrough compresses before the count does. And whatever is skipped is recorded as skipped with a pick-up date, exactly per 1.7. A pharmacist who has rehearsed the collapse does not improvise it badly on the day it happens.

Field notes. Teach what gets captured in the moment versus composed later. In the moment: exact numbers, names, times, locations, seal numbers, and the occasional verbatim phrase, because those are the things memory rewrites first. Later, same day: the finding itself, built from the captures per Module 4. Photographs follow facility policy and never contain PHI. A pharmacist writing findings from adjectives instead of captures produces the weak versions in Handout D-5.

How you know it landed. Given a described observation, the pharmacist places it in the right phase, assigns a severity they can defend, and states what the finding must contain.

Module 4 · Documentation and the record

Who needs this. Everyone, and it is the module that most often gets skipped because it feels like clerical work. It is not. It is the module that determines whether any of the other eight survive contact with a surveyor.

The governing idea. The record is the deliverable. A visit that cannot be reconstructed from the record did not happen, as far as anyone evaluating it later is concerned. The pharmacist's memory is not evidence, and it will not be available in three years.

Writing a finding

Taught by comparison. Weak and strong versions of the same finding, side by side.

Weak: "Temperature logs incomplete."

Strong: "Refrigerator temperature log for the main drug room is missing readings on 4 and 5 August. Facility policy requires twice-daily recording. Two of the four missed readings fall on a day when a temperature-sensitive product was administered."

The difference is not length. The strong version is falsifiable, dated, attributable to a rule, and carries the reason it matters. Handout D-5 carries five more pairs, across five different phases.

The five required elements, from section 1.6, and practice until they are automatic.

Narrative summary

Two to five sentences. Specific praise, honest concern, forward view. Written for an administrator, not a pharmacist.

Practice constraint: write it as if the reader is the facility's medical director, who is a physician, is not a pharmacist, and will read it once.

Amendments

The original is never altered. A correction creates a separate, co-signed amendment record, and both persist.

Teach why: a record that can be changed without a trace is not evidence. Facilities will ask you to "just fix" an entry, and the answer is that fixing it that way destroys the value of every other entry.

What not to write

- Speculation about individuals. Document behaviour and pattern, never a conclusion about a person you have not investigated.
- Diagnostic language about diversion in a routine record. There is a process for a suspicion, and a visit note is not it.
- Anything you would not want read aloud, because it will be.
- Debug or system text in a regulatory record.

How you know it landed. Given a rough observation, the pharmacist produces a finding another

pharmacist could act on without asking a question.

Module 5 · Controlled substances in depth

Who needs this. Everyone, and it is the longest module.

Perpetual inventory mechanics. What a correct one looks like, how entries should appear over time, and what a reconstructed one looks like. Uniform ink, uniform hand, and a month of activity in one sitting is a finding regardless of whether the arithmetic works.

Reconciliation method. Blind count first. Document the variance before investigating it. What a variance record must contain. What resolution requires, including reporting obligations, which are state-specific.

Discrepancy investigation. A sequence, taught as a sequence:

1. Document what was observed, before any explanation is offered
2. Preserve the records. Nothing is altered, including by helpful people
3. Determine the window in which it could have arisen
4. Establish who had access during that window
5. Interview, without accusing
6. Determine cause: documentation error, process failure, or loss
7. Report per state board and DEA obligations
8. Corrective action, and verify it took

Handout D-6 walks one variance through all eight.

Where it stops being yours. The moment a finding suggests an individual, it becomes a matter for facility leadership, counsel, and possibly law enforcement. Say this plainly in the module and draw the line before an investigation begins rather than during one. A consultant pharmacist who conducts an employment investigation has stepped outside their role and damaged the facility’s position.

Diversion red flags, grounded in pattern rather than paperwork:

- Waste consistently without a witness, or with the same witness always
- Quantities that do not match normal dosing for the procedure
- One person recording a disproportionate share of waste
- Discrepancies clustering around one person, shift, or location
- Records completed late, in batches, or after the fact
- Sign-outs with no corresponding administration or waste
- A pattern of small variances that individually round to nothing

The framing rule, and it is not optional. Nurses are the heroes of this module, never the suspects. Diversion detection protects staff at least as much as patients: an untreated substance use disorder in a colleague is a clinical tragedy, and a facility with no detection leaves it untreated. A pharmacist who arrives treating the nursing team as a threat will get nothing useful from them and will miss the thing they would have told you.

Waste and witness. Why a witness must authenticate as themselves. Why a credential entered by the person being witnessed is not a witness. Why an unwitnessed waste with a boilerplate justification, repeated, is a pattern an investigator recognizes immediately.

Destruction. Reverse distribution, retention, and why a draft that ages is itself a finding with an obvious and difficult question attached.

How you know it landed. Given a described variance, the pharmacist runs the eight-step sequence in order, names the reporting obligation for their state, and states where their role ends.

Module 6 · Running the standard in software

Who needs this. Everyone, in one of two versions.

For TOM pharmacists: the application as you will use it. Since-last-visit triage, visit checklist, verification queue and risk ordering, amendments, action items and CAPAs, reconciliation, case audits, diversion review, education log, and reports. The TOM MMS Pharmacist Operations Manual is this module's companion text: read it once end to end, then work from its queue and verification sections until they are habit.

For anyone running independently: the same functions in whatever system you use, including paper. See Appendix C.

The payload of this module is the same either way, and it is one distinction: which actions are authoritative and which are exploratory.

Authoritative actions carry your name, your judgment, and your license. Verifications. Reconciliation saves. Case approvals. Destruction signing. Amendment approvals. These are discoverable and attributable and they will be read by someone who was not there.

Exploratory actions do not. Reading a screen. Opening a record. Running a report to look at it.

Every pharmacist must be able to state, before finishing this module, which actions in their system are which. A pharmacist who cannot tell them apart will eventually perform an authoritative action believing it was exploratory, and that is the mechanism behind the mechanically cleared queue.

Session hygiene. An authoritative action happens with the source open beside it. A verification is performed against the underlying record, not against the summary line, and nothing is signed from memory, including the visit itself: the close in 1.7 is run with the record in front of you, box by box. The queue is worked in the risk order Phase 2 defines, and a select-all convenience is exactly the mechanism behind the mechanically cleared queue, which is why it is never used.

When the record and the shelf disagree, the instinct in software is to fix the data. Resist it. A system balance that does not match the shelf is a variance, and it enters the variance process from Module 5: documented as observed, then investigated. Editing the number to match the shelf is the electronic version of correcting the count, and it destroys the same evidence.

Downtime, and the two kinds of it. A lost network connection and a lost device are different failures and the standard treats them differently. TOM MMS installs as an app on the device and keeps capturing point-of-care entries when the connection drops, syncing them when it returns, so a short outage is not a paper event and staff should keep working rather than splitting the day across two record sets. A dead, lost, or locked-out device is the paper event: the Appendix C forms are the fallback set, kept where staff can reach them, with true event times written as they happen and transcribed later as late entries marked as entered late. Never backdated, never silently merged. Teach the distinction, because staff who reach for paper at every hiccup produce two half records that are harder to reconcile than one complete one. A downtime handled this way is a normal operational event with an honest seam in the record. Handled any other way, it is the place an auditor stops reading. Section 3.5 carries the full set of break-glass situations for the facility team.

Also covered: how to leave a visit incomplete honestly, since a system that makes incompleteness easy to record is a system that will get honest records.

How you know it landed. The pharmacist can list the authoritative actions unprompted and explain what each one asserts.

What good looks like. The arrival read, assembled before you walk in, is the difference between opening a visit and opening a filing cabinet.

```
TOM MMS   FACILITY  >  SINCE LAST VISIT
------------------------------------------------------------
Northside Surgery Center        last visit  4 weeks ago
------------------------------------------------------------
CS ENTRIES                412      discrepancies      1
TEMPERATURE READINGS      168      out of range       2
WASTE EVENTS               96      unwitnessed        0
CART CHECKS                28      seal events        1
------------------------------------------------------------
OPEN FINDINGS   6      overdue  2      oldest  41 days
NEW SINCE LAST VISIT
  . Discrepancy, hydromorphone, closed by facility
  . Expired stock found, PACU cabinet, open
------------------------------------------------------------
[  START VISIT  ]
```

Teach the reading, not the screen. The number that matters is not 412, it is the two overdue findings and the forty-one-day age, because a program’s health shows in what did not close rather than in what moved. The screen shortens the arrival; it does not do the judgment.

Module 7 · Communication and the facility relationship

Who needs this. Everyone, and it is the module that determines whether the other eight produce any change.

The core stance. Verify, educate, collaborate. The facility owns its compliance. Your job is to make owning it practical.

A consultant who positions as the compliance police gets treated like the compliance police, which means gets shown what the facility wants shown. You will find less, be told less, and the workarounds will be tidied before you arrive. The relationship is not a soft skill, it is an information-gathering control.

The first visit sets the frame, and it takes four sentences. This program belongs to the facility, and the findings are yours. My job is that nothing in this building surprises you: not a surveyor, not an investigator, not a bad day. I will tell you the truth in person before you ever read it in a report. And when I teach, it is because a facility that can run this without me is the goal. A pharmacist who opens that way gets shown the real building. A pharmacist who opens with a clipboard gets shown the tour.

Delivering a critical finding

In person, when you find it, not at the debrief and not in the report.

What works: state the observation factually, state why it matters, ask what they think happened, then agree what happens next. The question in the middle is not politeness. It frequently changes the finding, because they know something you do not.

What fails: leading with the rule, using the word “violation” when “gap” is accurate, delivering it to the wrong person, and saving it for the document because the conversation is uncomfortable.

When the facility disagrees with a finding, do not soften it and do not argue to win. Restate the observation, which is usually not the disputed part. Record their position, in their words, beside yours. If they decline the correction, the accepted-risk path in 4.4 exists for exactly this, and it converts an argument into a documented decision, which is usually the fastest way to end the argument. A disagreement documented honestly is a healthier record than an agreement performed reluctantly, and facilities respect the first far more than they admit.

Saying no

You will be asked to backdate, to soften, to leave something out, to verify something you did not review, and to sign a visit you did not complete. Usually by decent people under real pressure.

Practice the sentences in advance, because inventing them in the moment is how people say yes. Something like: I cannot record it that way, and here is what I can do instead. Then offer the alternative, because a no with a path forward is accepted and a bare no is resented. Handout D-7 is the card.

Answering what you do not know

Say you do not know, say when you will have the answer, and then have it by then. A consultant who bluffs once is discounted permanently, and the facility will not tell you that they have started discounting you.

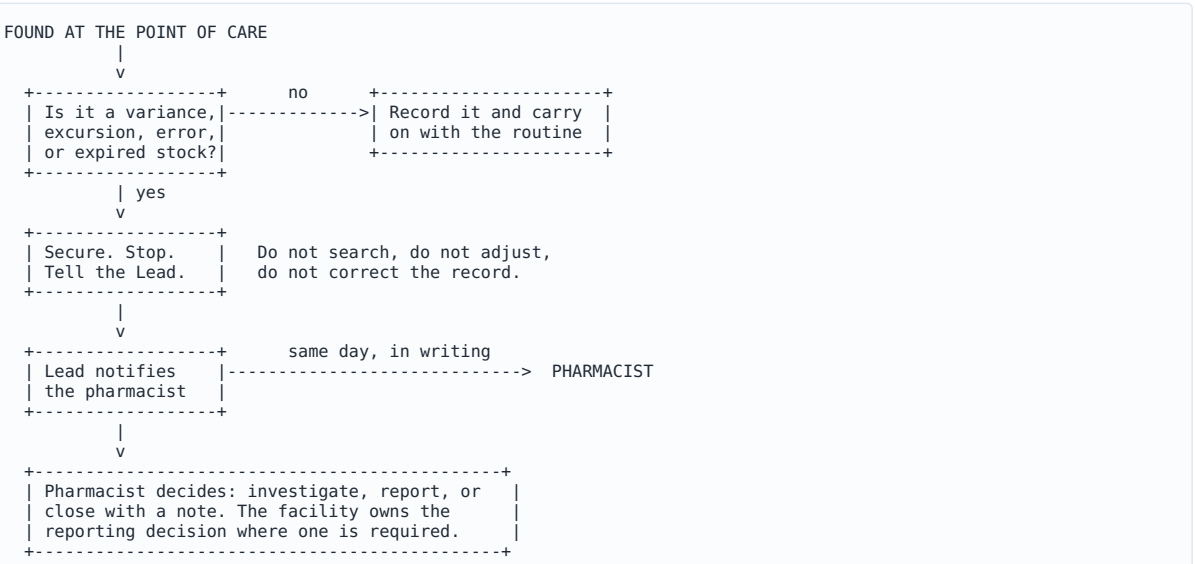
Who to talk to

Administrator, DON, medical director, Pharmacy Lead, anesthesia, and the nurse who actually opens the cabinet. Each hears the program differently and each tells you something the others will not. The nurse who opens the cabinet knows the most and is asked the least.

Opening the anesthesia conversation, since it is the one most often avoided. Do not open with their records. Open with their workflow: ask them to walk you through how a case's medications move from their cart to the patient to the waste, and listen for the twenty minutes it takes. The records conversation lands differently after you have understood the work, because it arrives as accounting for a workflow you respect rather than as an audit of one you have never seen. One good workflow conversation buys a year of cooperation.

How you know it landed. The pharmacist can deliver a hard finding in a role-play without either softening it into nothing or turning it into an accusation, and can produce a refusal sentence without hesitating. Handout D-23 carries the scenarios.

The escalation map, on one page. Post it where the Lead works and walk it in the session, because a path people can picture is a path people use.



Unsure belongs in the yes branch. Say that out loud in the session, and have the Lead say it back, because the branch people take when they are uncertain is the one that determines whether this map is real.

Module 8 · The business conversation

Who needs this. Every pharmacist, and especially the ones who assume it is someone else’s module. The clinical work earns the visit. This module is what makes the facility call between visits.

The premise. Section 5.2 named business judgment as the fifth function: an ASC’s drug line is a real cost, thin margins sit underneath it, and almost nobody in the building can read it. The pharmacist can, and a pharmacist who never does has left half the role unclaimed.

The five numbers, taught until they can be produced from a quarter of records without preparation. Each one is set out below the same way: what it is, why anyone should care, where the data actually lives, how to compute it, what a healthy number looks like, what an unhealthy one is telling you, and the sentence to say out loud.

1. Drug spend per case.

What it is: total medication spend for the period divided by the number of cases performed in the same period.

Why it matters: it is the only medication number an administrator can compare to anything. Total spend rises when volume rises and tells nobody anything. Spend per case isolates the part that is about how the building buys and uses drugs rather than how busy it was.

Where the data lives: spend comes from the wholesaler invoices or the purchasing report, and the case count comes from the facility’s scheduling or billing system, which means asking the administrator or business office rather than deriving it yourself. Use the same source every quarter, and say which source you used.

How to compute it: sum the invoices for the period, divide by cases. Trailing is more useful than a single quarter, so carry the prior period beside it. Exclude capital and non-drug supply if the invoice mixes them, and say that you excluded them.

What good looks like: stable or falling on flat case mix, with any movement you can explain in one sentence.

What a bad number is telling you: a rise on flat volume is one of four things, and naming which is the whole value of the number. A price increase you did not know about. A case-mix change toward more expensive procedures, which is not a problem at all. A utilization change, meaning more drug used per case. Or waste, which is the next number.

The sentence: “Spend per case is forty-one dollars against forty-four last quarter, on four hundred and twenty cases. The fall is one contract renewal on ropivacaine. Nothing else moved.”

2. Waste as a share of spend.

What it is: the value of medication discarded, expired, or wasted after preparation, expressed as a percentage of total spend.

Why it matters: it is the number that converts the pharmacist’s routine work into money an administrator can see, and it is the only line on the drug budget that is almost entirely controllable.

Where the data lives: the waste and expiry records the visits already generate. Expired stock pulled at the ninety-day horizon, controlled substance waste records, and single-dose vials discarded because of how they were purchased rather than how they were used. Price each item at acquisition cost from the invoice.

How to compute it: value of wasted and expired product divided by total spend for the same period. Split it into the two causes, because they have different fixes: waste at the point of care, which is a preparation and pack-size question, and expiry on the shelf, which is a par-level and rotation question.

What good looks like: a low single-digit share with the split named. There is no universal target, and inventing one would be dishonest.

What a bad number is telling you: concentrated expiry in one product is a par level set for a case mix the facility no longer runs. Concentrated point-of-care waste in one drug is usually a pack size mismatched to the dose actually used, which is a purchasing conversation, not a behaviour conversation.

The sentence: “Six percent of spend went to waste, down from seven. Two thirds of it is one drug where we buy a twenty millilitre vial and use four. Buying the five millilitre presentation would recover most of it.”

3. The top movers.

What it is: the three products whose cost changed most since the prior period, up or down, with the reason for each.

Why it matters: it turns a spreadsheet nobody reads into three sentences somebody can act on, and it is how a pharmacist demonstrates they are watching rather than reporting.

Where the data lives: line-level invoice history, sorted by absolute change in total cost rather than by percentage, because a large percentage swing on a cheap drug is noise.

How to compute it: period-over-period spend by product, ranked by absolute dollar change. Then do the work the number cannot do for itself: for each of the three, decide whether the driver was price, volume, or substitution.

What good looks like: every mover has a named cause and none of them is a surprise to you.

What a bad number is telling you: a mover you cannot explain means either the data source changed underneath you or something happened in the building you did not know about. Both are worth finding out before the meeting rather than during it.

The sentence: “Three things moved. Ropivacaine down on the new contract, ondansetron up on price with volume flat, and cefazolin up because we did more of the cases that use it.”

4. Par against use.

What it is: what the building keeps on the shelf compared with what it actually consumes over a representative interval.

Why it matters: it is where expiry comes from, where stockouts come from, and where a surprising amount of working capital sits doing nothing.

Where the data lives: the par levels in the storage location register, and usage from the medication records over a trailing quarter. This is the number software makes trivial and paper makes tedious, which

is why most facilities have never seen it.

How to compute it: for each product, months of supply on hand at current use. Then look at two tails rather than the average: items with many months of supply, which will expire, and items that went to zero or near zero, which threatened a case.

What good looks like: pars that were revised at least once in the last year, and a short list of exceptions each with a reason.

What a bad number is telling you: pars set at opening and never revisited while the case mix moved. That is the finding this element produces most often in this category and it is entirely benign in intent.

The sentence: “Three items are carrying more than a year of supply and will expire before we use them. One item ran to zero twice last quarter. Both are par decisions, and I have a proposed change for each.”

5. What is coming.

What it is: the medication events in the next quarter that will land on this facility whether or not anyone prepares for them.

Why it matters: everything else in this module explains the past. This is the one an administrator actually cannot get anywhere else, and it is the reason they take the meeting.

Where the data lives: contract and renewal dates from purchasing, the shortage feeds and recall notices from Module 9, manufacturer formulation and presentation changes, and the compliance calendar’s own dates such as license renewals and the biennial.

How to compute it: there is no computation. There is a list, kept between visits, filtered to the items that touch this formulary and this building.

What good looks like: two to four items, each with a date and a recommended action.

What a bad number is telling you: an empty list means you are not watching, not that nothing is coming.

The sentence: “Two things are coming. The ondansetron contract renews in November, and there is a shortage signal on a drug we keep in the crash cart. I would like to agree the alternative before it bites rather than after.”

The habit underneath all five. Compute them the same way every quarter, from the same sources, and say which sources. A number that moves because you changed how you measured it is worse than no number, because it spends credibility you will need later.

Translation discipline. Dollars, not doses. Every number carries its denominator, because “spend is up” means nothing and “spend per case is up eight percent on flat volume” is a finding. Nothing lands in writing that was not raised in person first, which is the same rule the debrief already follows.

The quarterly business conversation. Fifteen minutes with the administrator, standing on the leadership summary’s fifth question: what spend did, what drove it, the one decision worth making, and what is coming. One recommendation, with its tradeoff stated, beats five observations.

What this is not. Not a promise of savings, which nobody can promise. Not purchasing consultancy that displaces the compliance half, per 5.2’s both-halves rule. And never clinical cost-cutting: a conversation

about a drug choice includes the clinical frame and the people who own it, or it does not happen.

Speaking the administrator's own metrics. The five numbers above are the pharmacist's contribution. They land better when the pharmacist also understands what the administrator is already measured on, because a medication number offered inside their frame is a number they can use.

What the administrator tracks	What it means to them	Where medication touches it
Case volume and case mix	The denominator under everything else, and the driver of revenue	Every number in this module needs the case count, so ask for it rather than estimating
First-case on-time starts	A visible daily measure, watched closely, with many causes	A missing or unavailable medication is one of those causes, and it is one the pharmacist can remove
Turnover time	Capacity, and therefore money	Medication steps sit inside turnover. A cabinet down the hall is a turnover problem as well as a records problem
Cancellations	Lost revenue and a bad patient experience	Rare, but a drug shortage or an unavailable agent cancels cases
Cost per case	The number the owners see	Drug spend per case is a component of it, and usually the only component nobody has explained
Supply and pharmacy expense as a share of revenue	Budget performance	This is where the waste number goes to work
Staffing hours per case	The largest cost line in the building	Time nurses spend on medication paperwork is staffing cost, even though it never appears on the drug budget
Patient safety events and near misses	Risk, and the QAPI program	Medication events are a named category, and 6.6 is how they get reported
Survey and accreditation readiness	An existential worry that surfaces in cycles	The medication layer is a large share of what a surveyor reads first

What QAPI actually is, from the administrator's side. Section 6.6 gives the pharmacist's contribution to it. This is the frame that contribution sits in. A Medicare-certified surgery center must run a quality assessment and performance improvement program that is data-driven and ongoing, measures indicators, tracks adverse patient events, shows measurable improvement, and reports to a governing body that owns the results. In practice that means the administrator needs, every period, indicators with denominators rather than counts, a small number of improvement projects with baselines and results, and evidence that leadership saw it and acted.

Why this matters to a pharmacist. Most administrators are assembling that packet from several

departments, and the medication section is usually the thinnest because nobody owns it. A pharmacist who arrives with six trended indicators, a documented improvement project, and two sentences per indicator has not added work to the administrator’s quarter. They have removed a section of it. That is the difference between being a cost line and being the reason the quality packet is finished on time.

The three questions to ask at the first business conversation, because the answers shape every number afterward: which indicators does the governing body already see, when does the quality committee meet, and who assembles the packet. Then deliver into that shape rather than inventing a parallel one.

Handout D-8 is the five numbers, with the sentences.

How you know it landed. Given a quarter of records, the pharmacist presents the two numbers that matter in two minutes, in administrator language, with denominators, and answers “so what should we do” with one recommendation and its tradeoff.

What good looks like. The five numbers, assembled, with their denominators attached, so the conversation starts at meaning rather than at arithmetic.

```
TOM MMS   REPORTS  >  QUARTERLY SUMMARY
------------------------------------------------------------
Northside Surgery Center            Q3          420 cases
------------------------------------------------------------
MEDICATION SPEND PER CASE      $ 41.20     prior  $ 44.10
WASTE AS SHARE OF SPEND           6.1 %    prior    7.4 %
TOP FIVE BY SPEND              ropivacaine, ondansetron,
                               cefazolin, propofol, fentanyl
PAR vs USE                     3 items overstocked
                               1 item short twice
WHAT IS COMING                 2 renewals, 1 formulation
                               change, 1 shortage on list
------------------------------------------------------------
[  EXPORT  ]     [  ADD MY TWO SENTENCES  ]
```

The export is not the deliverable. The two sentences are. Module 8’s whole discipline is that a number without its sentence is data an administrator has to interpret alone, which is the job they were hoping to hand to someone.

Module 9 · Proactive practice

Who needs this. Everyone, and it is the module that changes what the facility thinks a pharmacist is for.

The stance. A reactive consultant reports what happened. A proactive one changes what happens next. Findings are the floor of this job. The ceiling is a facility that stopped generating certain findings because the pharmacist saw them coming.

The forward calendar. Expirations inside ninety days, the survey window, the accreditor's standards version, the board newsletter and the legislative session, the federal biennial due date, contract renewals, and staff turnover that will become a training finding if nobody moves. Every item carries a date and an owner before it is urgent, which is the entire difference between a calendar and a crisis.

Horizon scanning, concretely. FDA shortage and recall feeds read against this facility's formulary, not against the news. MHAUS guidance against the cart actually stocked. The accreditor's published deficiency data against this facility's own record. A scan without the formulary next to it is reading the news.

The three-item rule. Every debrief carries at least three forward items nobody asked for. Section 8b already ends the debrief with "what is coming"; this module makes it a discipline with a floor.

Anticipatory findings. The Informational-with-a-date class, worked as case 10 in Handout D-3. Writing tomorrow's Critical as today's Informational with an owner is the cheapest work in the program, and it is the work facilities remember at renewal.

What proactive is not. Alarmism, hedged everything, or manufactured urgency. A forward item has a date, a source, and an owner, or it is a worry, and worries do not go in the record.

Handout D-9 is the forward calendar card.

How you know it landed. The last three debriefs each contained forward items with dates and owners, and at least one finding this quarter was written before it happened rather than after.

Working into independent visits

Inside TOM: two visits observed, then two visits led with an experienced pharmacist present, then the first four independent visit records reviewed before the pharmacist works unsupervised.

Four records, not one. The failure mode is a good first record and drift by the fourth. Handout D-24 is the record of the whole sequence.

Independently, the equivalent is finding someone to read your first few records who will tell you the truth about them.

Staying current

Annual, and lighter than the initial pass: license verification, HIPAA retraining on the applicable cycle, a review of what changed in the standard, and a look back at two of your own visit records from the year.

Reading your own year-old record is the most useful hour in this program. It is where drift becomes visible.

Standard of practice

Inside TOM, four behaviours end the working relationship, stated openly at the start rather than buried: signing for work not performed, clearing a verification queue mechanically, falsifying a record, and any conduct that would embarrass a facility that trusted the signature.

Independently, these are still the four. There is simply nobody to enforce them but you, which is a harder standard and not an easier one.

2.4 Records retained

For each pharmacist: the five prerequisites, module completion dates, the supervised-visit log, record review results, and license verification history. Handout D-24 is the one-sheet instrument for it.

For each Facility Pharmacy Lead: competency by topic with dates, refresher history, and the facility’s own copy.

These records are the evidence layer. Training whose completion cannot be evidenced is indistinguishable from training that did not happen, which is the same standard applied everywhere else in this document.

Running this without software

Training records are the easiest thing in the program to keep and the easiest to lose. A session happens, attendance is captured on a sheet, the sheet goes in a folder, and eighteen months later a surveyor asks which of your current staff completed diversion awareness and when. The answer is in the folder, in an order nobody designed, missing the three people who were hired since.

The work is not the training. It is knowing, at any moment, who is current and who is not, and being able to show it without assembling it.

TOM MMS holds the education log and attendance as records rather than as documents, so competency currency is a query instead of a search. You can run this on paper. Most facilities do. It is also the point where most facilities quietly cannot answer the question when it is asked.

PART THREE

Training the Facility Team

PART 3 · TRAINING THE FACILITY TEAM

What this part is for. The pharmacist is in the building for a small fraction of the hours in which medications are handled. Everything that happens in the other hours is done by facility staff, and almost every record the pharmacist later reviews was created by them. This part is the training for those people, and it can be printed and handed over on its own.

Read it in this order. What the Lead role actually is, then how to choose and develop the person who holds it, then the eleven topics they and their team are taught, then the routine they run between visits. Choosing comes before teaching on purpose: a curriculum delivered to the wrong person, or to a person given no time, fails in a way no amount of teaching content repairs.

Inside: the Facility Pharmacy Lead, choosing and developing the Lead, the eleven-topic curriculum with its competency checks, the daily, weekly, and annual routine, and what to do when that routine breaks.

3.1 The Facility Pharmacy Lead

Who this is

One designated staff member per facility, usually a nurse, who owns the daily medication routine between pharmacist visits. Named, not assumed. A facility where everyone owns the routine has nobody owning it.

This is the most consequential person in the program and the one most programs never train. The pharmacist is present for a small fraction of the hours in which medications are handled. The Lead is present for nearly all of them. Every record the pharmacist reviews was created by the Lead or by someone the Lead influences.

Choose deliberately. The right person is not necessarily the most senior nurse or the one with the most availability. It is someone who is present most days, is respected enough that a correction from them sticks, and is temperamentally willing to say “I do not know” rather than guess. That last trait matters more than experience.

Name and train a deputy, not just a name on a form.

A single point of failure who takes two weeks of leave takes the routine with them, and the gap does not announce itself. Logs get thinner, escalations stop, and nobody notices until the next visit.

The deputy completes the same curriculum as the Lead. Not a shortened version, because the situations that most need the deputy are the ones the Lead usually handles, which means the deputy meets them cold and rarely.

Rotate deliberately. Have the deputy run the routine for a full week at least twice a year, with the Lead present but hands-off. Two things come out of it: you find out whether the training took, and you find out what the Lead has been doing that nobody wrote down. The second one is usually the more valuable discovery, and it is how the routine stops living in one person’s head.

In larger centers, consider a third. Two people covering a seven-day operation with holidays and turnover is thinner than it looks on paper.

What the role actually owns

Write this down at the facility, because a role nobody has defined is a role nobody can hand over.

- The daily and per-shift medication routine happens and is recorded
- Gaps are noticed and escalated rather than absorbed
- New staff learn the routine deliberately rather than by observation
- The facility is ready for the pharmacist visit
- Findings assigned to the facility get done, or get escalated when they cannot
- Supplies, logs, and forms exist before someone needs them

What the role does not own: pharmacist judgment, any determination about whether something is compliant, and any decision about a controlled substance discrepancy beyond documenting and escalating

it.

3.2 Choosing and developing the Lead

The curriculum in 3.1 makes a Lead competent. This section is how one gets chosen, brought up, corrected, kept, and replaced, because the role fails far more often from neglect than from ignorance.

Choosing

The facility appoints; the pharmacist advises. What to advise for:

- **Present for the routine**, on the shifts and days the medication work actually happens. A Lead who is rarely in the medication room cannot verify a routine, whatever their title says.
- **Trusted by peers rather than senior to them.** The role runs on people telling the Lead inconvenient things quickly. Authority helps less than approachability here.
- **Comfortable saying a number out loud that does not match.** This is the single best predictor, and it is worth asking about directly in the conversation before appointment.
- **Willing, not conscripted.** A Lead who inherited the job in a meeting they missed will do the parts that are visible and skip the parts that are not.

What to advise against, gently: the person who already carries three other collateral duties, and the person whose instinct on a discrepancy is to find the drug rather than to secure the record. The second one is trainable, but not while they are learning everything else.

Name a deputy at the same time. A single point of failure with keys and a checklist is not a program, and the deputy trains alongside rather than being briefed later.

Beyond the floor. No regulation requires a named deputy. This standard does, because the most common way a medication routine collapses is not misconduct, it is the only trained person leaving, going on leave, or moving to nights. A deputy trained alongside the Lead rather than briefed afterward is the difference between a program that survives turnover and one that restarts.

The first ninety days

Stage	What the Lead does	What the pharmacist does
Appointment	Reads the topics that touch their daily work; shadows the current routine	Sets expectations with the administrator in writing: time required, authority granted, and who backs them up
Early weeks	Runs the daily routine with the pharmacist’s checks alongside; starts the between-visit list	Teaches Session A and B from Handout D-22; answers questions same day, every time, without exception
Middle	Verifies rather than performs; runs the weekly review; begins teaching one topic to a peer	Watches a teach-back; corrects method rather than content; records competency by demonstration
End of the ramp	Owns the routine, escalates cleanly	Confirms competency across the

End of the ramp	Owns the routine, escalates cleanly, arrives at visits with their own list	Confirms competency across the topics, names the deputy's status, and tells the administrator plainly whether the role is working

The teach-back is the milestone that matters. A Lead who can teach Topic 1 to a new nurse has understood it; a Lead who can only perform it has memorized it, and memory does not survive turnover.

Coaching, in the moment

Most correction is thirty seconds long and happens beside the work. The shape that keeps it useful:

1. **Name the behaviour, not the person.** "This entry went in after the case" rather than "you are behind on your logs."
2. **Say the consequence once, concretely.** "If a count comes up short tomorrow, this entry cannot tell us when the drug left."
3. **Ask what got in the way.** Almost every workaround in C.4 has a real cause sitting behind it, and the cause is usually fixable.
4. **Agree the change out loud**, small and specific, then check it at the next visit, because a correction nobody returns to was a comment.

Correct privately, praise where others can hear it. The reverse teaches the room that the routine is enforced by embarrassment, and a routine enforced by embarrassment produces hidden problems.

What not to do: correct across a sterile field, correct in front of a surgeon, correct a nurse for something the schedule made inevitable, or save up five observations for a quarterly conversation. Saved-up corrections land as a verdict on the person.

When the Lead is struggling

Sometimes the routine fails at the Lead. Section 1.2 governs how that gets handled, and it changes the first question: not what is wrong with this person, but what did this program fail to give them. Ask it honestly before anything else, because the answer is usually a real one. Were they given time, or is the routine expected to happen inside a full clinical assignment. Did the training land, or did they attend a session and never teach it back. Were their escalations answered, or did the first two go into silence. Is there a deputy, or have they carried it alone for a year. Each of those is a failure of the program rather than of the person, and each of them looks identical from the outside to somebody who simply is not doing the job.

Start by asking rather than concluding, and ask them directly and privately. "The counts have not been recorded for two weeks and I want to understand what got in the way" is a different conversation from "the counts have not been recorded." The first one usually produces the actual cause. The second produces a defence.

Only after that question has a real answer does the sequence below apply, and the sequence is the same discipline this document uses everywhere: observe, document, support, escalate, and stay in your lane.

1. Verify it is real, from the record rather than from an impression. Then separate three things rather

than two: **was not able to**, which is a training or a workload finding and belongs to you to fix; **was not supported**, which is a program design finding and also belongs to you; and **is choosing not to**, which is a facility personnel matter and does not belong to you at all. The first two are far more common than the third, and assuming the third first is the fastest way to lose a Lead who was recoverable.

2. Raise it with the Lead first, in the coaching shape above, and give it a defined interval to change.
3. If it does not change, it goes to the DON or administrator as a program risk, in writing, describing behaviour and consequence, not character. Per 5.9, the pharmacist does not manage facility staff and does not recommend discipline.
4. Where the role has to change hands, the handover in 2.4's records and the competency file make the transition survivable, and the deputy is why the routine does not stop while it happens.

The failure to watch for is quieter than refusal: the Lead who is willing and drowning. That one is the facility's staffing decision, and naming it early as a workload problem rather than a performance problem is usually what saves the program and the person.

Keeping the Lead

Turnover in this role is the most common cause of program decay this document sees, and almost all of the retention levers are cheap.

- **Say what the role is worth to them.** Competency records, a documented specialty responsibility, and teaching experience are real professional assets, and most Leads have never been told that.
- **Protect the time.** A Lead expected to run the routine inside a full clinical assignment will drop the routine, correctly, because the patient in front of them wins.
- **Answer quickly.** A Lead who has waited three days for an answer twice will stop asking and start deciding, which is the precise outcome the role exists to prevent.
- **Close the loop visibly.** When a Lead's escalation produced a fix, say so where the team can hear it. The role's authority is built out of visible consequences.
- **Debrief them before you debrief the administrator**, so they are never surprised by a finding in their own area.

In TOM MMS the competency register and the training records are the artifacts this section runs on, which means a Lead's development has a record rather than a reputation.

PART 3 · TRAINING THE FACILITY TEAM

The Eleven Topics

3.3 The curriculum

Each topic ends with the person able to do the thing, not describe it. Teach at the cabinet where practical, not in a conference room. The handouts in Appendix D.2 are the cabinet-side companions to these topics: print them, post them, and teach from them where the work happens. Handout D-22 is the session plan for delivering the eleven topics as three cabinet-side sessions. Facilities running TOM MMS pair the curriculum with the TOM MMS Nurse Operations Manual, which is the software side of the same routine and travels in the onboarding packet. Where a topic maps to a point-of-care task, the topic carries the procedure itself, step by step, and the italic line beneath it names how TOM MMS runs the same steps, because the standard and the software were built together.

Topic 1 · Controlled substance logging

Why this exists. Almost every controlled substance record in the building begins with an entry the Lead or a nurse makes. The pharmacist reviews those records; this topic is where they are made well enough to survive review, and review by people far less friendly than the pharmacist.

What to teach. Every entry type: sign-out, administration, waste, return, transfer. What each one proves. A sign-out proves who took custody, for whom, on whose order. An administration proves the dose reached the patient it was signed out for. A waste proves the remainder went nowhere, witnessed. A return proves custody came back intact. A transfer proves the chain has no gap in it.

Then the fields, one at a time, with the why beside the what. The patient identifier ties the entry to a case that actually happened that day. The ordering practitioner must be someone who was in a position to order it. The quantity is written in the units the sheet uses, because a milligram entered in a milliliter column is a variance waiting to be discovered. The time is the time of the event, not the time of the writing. The signature is the person who did it, never a colleague being helpful.

Corrections are amendments. On paper: one line through the error, the correction beside it, initials and date, nothing obscured. An entry scribbled out or written over is worse than the error it replaced, because it looks like concealment even when it is not.

The sign-out, step by step. At the point of care, at the time of the pull, never batched:

1. Initiate the sign-out before or as the medication leaves its storage location.
2. Choose the method: a protocol pull takes the pharmacist’s predefined bundle for the procedure type; an individual sign-out takes one medication at a time. Use the protocol when one exists; it is the pre-checked list.
3. Identify the exact product against what is physically in hand, and read the warnings before proceeding: the schedule, any high-alert designation, any look-alike sound-alike caution. The warning is a checkpoint, not a decoration.
4. Complete the required captures: the patient identifier, never the name; the ordering practitioner; the pull location, named exactly as the facility’s location list names it; the quantity in the record’s units. For any Schedule II medication the prescription or order number is mandatory, and the sign-out is not complete without it.
5. Mark a late entry honestly, carrying the true event time. A late flag on an honest record is correct; an on-time-looking record with a false time is what investigators are trained to find.
6. Submit and read the confirmation back: patient, practitioner, drug, location. Three seconds of reading catch the transpositions that become tomorrow’s variance.
7. Choose the next step deliberately: the waste for this case, the next case, or close out. The choice keeps back-to-back cases fast without letting speed skip the waste.

The stop rule. A sign-out that cannot be completed correctly stops. Missing order number, unknown practitioner, product that does not match the order: resolve first, sign out second.

What good looks like. The screen below is the sign-out as it should appear at the moment of the pull, with the running balance visible before the entry is made rather than discovered later.

```
TOM MMS   CONTROLLED SUBSTANCE  >  SIGN OUT
------------------------------------------------------------
CASE / PATIENT   [ Case 4   .  Room 2                    v ]
DRUG             [ Fentanyl 100 mcg / 2 mL               v ]
LOCATION         [ Main CS safe                          v ]
QUANTITY         [ 1 ] vial
------------------------------------------------------------
ON HAND NOW              47        AFTER THIS ENTRY   46
LAST ENTRY               by R. Ellis, RN
------------------------------------------------------------
(!)  SCHEDULE II   witness required at waste
------------------------------------------------------------
      [  CANCEL  ]                   [  SIGN OUT  ]
```

What to notice, and what to teach from it: the expected balance is on the screen before the entry, so a count is a comparison rather than a memory test; the case is attached at the pull rather than reconstructed; the schedule flag warns about the waste requirement before the drug is in anyone’s hand; and there is no field anywhere for a time the person types themselves.

In TOM MMS this is the Sign out drug workflow: the entry asks for an identifier rather than a patient name, the Schedule II order number is a hard gate, late entries carry their flag and true time, and a quick-repeat shortcut carries the same drug to the next case in one step.

Teach it at the cabinet. Blank C-5 sheet, five scenario slips, one per entry type. Each learner records all five, live, with the balance run line by line. Then hand them a deliberately wrong entry and have them correct it as an amendment.

Where it goes wrong. Batching entries at the end of a shift, which turns a record into a reconstruction. Initialing for someone else. Quantities in the wrong units. Skipping the return entry because the drug “just went back.” Each of these is common, each feels harmless, and each is the exact thing an investigator circles.

The point to land: this log is the facility’s proof of where every controlled substance went. An entry that is incomplete is not a paperwork gap, it is an unaccounted quantity of a controlled drug.

Demonstrates: records all five entry types correctly, unprompted.

Handout D-10 is the card, and Form C-5 is the sheet it feeds.

Topic 2 · Witnessing

Why this exists. A witness signature is the strongest control in the controlled substance system and the one most casually destroyed. Every shortcut in this topic feels like teamwork in the moment and reads like fraud on paper.

What to teach. What the signature attests: I personally watched this happen. Not “I trust her.” Not “I was nearby.” Not “she asked me to.” The attestation is about your own eyes at the moment of the event, and it is recorded under your name, permanently.

The three rules, in order. Your credential never leaves your hands, not your PIN, not your badge, not for anyone, not for a minute. You witness at the moment, because a waste witnessed later is a story. You sign only for what you actually saw, and if you looked away, you say so and it is done again.

The senior-in-a-hurry script, practiced out loud until it is automatic: “I can’t enter my credential for you. I’ll come witness it right now.” The offer to come now is the whole answer. It solves their problem and keeps the record true, and seniority does not change what a witness is.

Why this protects your colleague. Shared credentials are the pattern that makes diversion invisible, and invisibility is what keeps a colleague with a substance problem in trouble until something irreversible happens. Witnessing properly is not suspicion. It is the protection working.

The waste, step by step. Immediately after the case, before the next one starts:

1. Initiate the waste directly from the case’s sign-out wherever the record links them, so the waste attaches to the custody chain it closes.
2. Record the amounts, administered and wasted, or state explicitly that the full dose was used. The amounts must reconcile against the quantity signed out; a gap is a variance, not a rounding matter.
3. Bring the witness to the moment: a second authorized person watches the actual disposal into the actual receptacle and attests with their own credential, physically present, never lending a PIN, and never the same person who signed the drug out.
4. Complete the record only after the witness has attested. A waste saved before the witnessing happened is a false record even when the waste itself was done properly.

The return variant. An unopened, tamper-evident unit going back to stock is a return, not a waste: record it to its named location so the balance recovers, and never return an opened or partial unit to stock.

The stop rule. No witness available means the waste waits, secured, in the custody of the person who signed the drug out, and a more than momentary wait is documented.

What good looks like. The waste screen holds its save until a second person is genuinely present, which is the whole control in one interaction.

```
TOM MMS   CONTROLLED SUBSTANCE  >  WASTE
------------------------------------------------------------
FROM ENTRY   Fentanyl 100 mcg / 2 mL    .   Case 4
DISPENSED    100 mcg          ADMINISTERED  [  70 ] mcg
                              WASTED         30 mcg
METHOD       [ Wasted into approved receptacle          v ]
------------------------------------------------------------
WITNESS
   [ Select witness                                     v ]
   PIN  [ * * * * ]
   Witness must be a different person than the signer.
------------------------------------------------------------
[  SAVE  ]   disabled until witness authenticates
```

What to notice: the arithmetic is done by the screen, so the number being witnessed is not in dispute; the witness authenticates rather than signs, which is what makes a courtesy signature impossible; and the save control is visibly disabled, which teaches the rule better than a policy sentence does.

Beyond the floor. The requirement is that waste be witnessed. This standard requires that the witness be identified at the moment of the waste by their own credential rather than by a signature added later, because a signature collected afterward proves only that someone was willing to sign.

In TOM MMS this is the Waste / return workflow: the save control stays disabled until a second authorized person enters their own PIN or badge, the system rejects the signer's own credentials as witness, and the Complete waste for this case shortcut keeps the waste attached to its case.

Teach it at the cabinet. A briefed colleague makes the ask: "I'm slammed, just punch in your PIN." The learner refuses and offers, in their own words. Then reverse the roles, because everyone will be on both sides of this eventually.

Where it goes wrong. Courtesy witnessing, where the signature happens and the watching does not. Pre-signing before the waste. Witnessing from the doorway. Each one converts the strongest control in the system into decoration.

Demonstrates: can explain in their own words why they would refuse to hand over their credential, even to someone senior and in a hurry.

Handout D-11 is the cabinet-side card.

Topic 3 · Temperature logging

Why this exists. The refrigerator is where a quiet failure destroys the most inventory, and the log is the first thing a surveyor opens. The reading is the easy half. What happens after a bad reading is the half that decides whether this facility looks like it manages medications or merely stores them.

What to teach. The cadence, and why a gap is a finding even when every recorded value is fine: a silent gap is indistinguishable from a reading nobody wanted to write down. The range, in the units the policy uses, checked against the units the log uses, because a log in Fahrenheit judged against a policy in Celsius is a defect that survives for months.

The logging steps. The reading itself, done right:

1. Open the log for the specific unit; the unit's own acceptable range and location are stated where the reading is entered.
2. Enter the actual reading, never rounded, in the units the log uses.
3. An in-range reading saves plainly and lands on the day's record.
4. An out-of-range reading does not save without a corrective-action note: what was done, who was told, when. Write the real note, because the note is the point.

What good looks like. Out of range is not an error message, it is a different screen that asks for the response before it will let go.

```
TOM MMS   STORAGE  >  LOG TEMPERATURE
-----------------------------------------------------------
UNIT     [ Med room refrigerator            v ]
RANGE      2 to 8 C                READING  [ 9.4 ] C
-----------------------------------------------------------
(!)  OUT OF RANGE
     WHAT DID YOU DO?  (required)
     [ Door found ajar, closed it, moved nothing, told  ]
     [ the Lead, rechecking in 30 minutes               ]
     AFFECTED STOCK   ( ) none   (o) quarantined
-----------------------------------------------------------
[  SAVE  ]      escalation to pharmacist  ON
```

What to notice: the reading is recorded even though it is bad, which is the behaviour a program wants; the corrective note is required at the moment, not at the end of the day; quarantine is a recorded state rather than a taped note; and escalation happens because the record happened, not because someone remembered to mention it.

In TOM MMS this is the Log temperature workflow: each unit displays its range, an out-of-range value locks the save until the corrective-action note exists, and a documented excursion handled well is exactly what a surveyor wants to see.

When a reading is out of range, the six steps, in order: record the real number, never rounded into range. Note the duration if it can be known. Set the affected stock apart, marked, not used. Notify the Lead now, and the pharmacist the same day if any temperature-sensitive drug is involved. Write the corrective action beside the reading, with who and when. And the pharmacist decides usability, not nursing, not the refrigerator feeling cold again.

What a good corrective action reads like. Cause, action, person, time. "Door found ajar after 0630

restock; closed, stock quarantined, Lead notified 0710, pharmacist consulted same day.” Four facts. A blank in that column is a facility that noticed a problem and did nothing, which is the worse finding.

Teach it at the unit. Run a live check. Then hand the learner a log with a planted out-of-range value and watch the six steps happen without prompting.

Where it goes wrong. Rounding into range. “It’s fine now” as a corrective action. Quarantine skipped because the stock is expensive. The blank column.

The point to land: the corrective action is the important part. A missed reading is a gap. An out-of-range reading with a blank corrective action is a facility that noticed a problem and did nothing, which is worse and reads worse.

Demonstrates: records a reading, identifies an out-of-range value, and executes the corrective action path without being prompted.

Handout D-12 is the postable version of the path.

Topic 4 · Cart and box checks

Why this exists. Emergency equipment is low frequency and high consequence, which is exactly the combination that degrades quietly. Nothing goes wrong for years, the checks get thinner, and the day the cart is needed is the day the check finally matters.

What to teach. What a seal is: a claim that nothing inside has changed since the last full check. The whole check hangs on that claim, which is why the seal number is read off the seal, every time, and never off yesterday's log line. A number copied forward is a false claim about emergency equipment, and it is the kind an auditor finds in one pass.

The check itself: seal present, number recorded fresh, intact. The equipment sub-checks the policy requires: defibrillator status, pads in date, battery, oxygen, suction. The contents list version, because a cart checked against the list it shipped with is checked against a different cart.

The check, step by step. At the cart, not at the log:

1. Verify the cart's identity and location against the record being made.
2. Read the seal number off the physical seal and record it fresh; a number copied from yesterday's line is a false claim.
3. Confirm the equipment attestations reflect reality, the defibrillator status among them. A checkbox is an attestation, not a formality.
4. A broken seal or failed equipment is an incident: report it and follow the restocking procedure; never check the box falsely to keep the day moving.
5. Save the check; it lands on the day's record with its seal number.

What good looks like. The seal number is typed from the seal in front of you, and yesterday's number is deliberately not shown while you type.

```
TOM MMS   CARTS  >  CHECK CART
------------------------------------------------------------
CART      [ Crash cart, PACU                v ]
SEAL NUMBER READ FROM THE CART   [ 0 4 8 2 3 1 ]
------------------------------------------------------------
[x] Seal intact and matches
[x] Contents list version current
[x] Defibrillator, pads in date, battery charged
[x] Oxygen and suction present, cart reachable
[ ] Broken or missing seal    -> opens entry report
------------------------------------------------------------
[  RECORD CHECK  ]
```

What to notice: the sequence is read the seal, then type it, which is the opposite of the habit that produces copied numbers; each checkbox is an attestation by a named person rather than a tick on a shared sheet; and the broken-seal path is on the same screen, so the exception is one tap away instead of a conversation about who to tell.

In TOM MMS this is the Check cart workflow: the seal number is typed from the physical seal, the intact and equipment checkboxes are attestations, and the incident report routes a broken seal straight to the pharmacist.

When the seal is broken, missing, or mismatched: stop. Record the old number and the condition

found. Full internal check against the current list, not a glance. Restock and document. New seal, new number, recorded, Lead and pharmacist notified. A broken seal with a documented check is a normal day. A broken seal with a carried-forward number is a finding.

Teach it at the cart. Run a live check with the seal number deliberately mismatched against the log. The learner should notice without being told, stop, and state the sequence.

Where it goes wrong. Copying yesterday’s number. Checking the log instead of the cart. Resealing after a code without the full internal check. A contents list nobody has versioned.

The point to land: recording a seal as intact without looking at it is a false claim, and it is a claim about the cart the facility will reach for on its worst day.

Demonstrates: completes a check, records the seal number, and states what happens next if the seal is broken.

Handout D-13 covers the broken seal.

Topic 5 · Expired and beyond-use dating

Why this exists. Two different clocks run on every vial, and confusing them is the most common storage defect in the building. One of the two mistakes is housekeeping. The other has put patients in the hospital.

What to teach. The manufacturer expiration is on the label and applies to the unopened container. The beyond-use date starts when a container is opened, entered, or a dose is drawn, and it is almost always sooner than the label date. The label date never rescues an opened vial.

The four rules. A multi-dose vial is dated when first entered, on the vial, at that moment, and discarded at the beyond-use date in facility policy even if the label date is months away. A single-dose vial is one patient, one use, never retained, and this is the most commonly broken rule in the building and the one with real infection-control consequence behind it. Anything drawn in advance is labeled with a beyond-use time and discarded at it. And an opened, undated vial is discarded, not estimated, because undated means unknown and unknown loses.

The policy states the number. The interval itself lives in facility policy against the state’s rules, which is why this topic teaches the rule and not a day count. Staff state the policy; if they cannot, the Lead asks the pharmacist, and knowing where the answer lives counts as knowing.

Teach it in the storage areas. Plant one expired vial and one opened, undated multi-dose vial, then walk the cabinet with the learner. The plants are the exam, and the back row is where they go, because rotation fails from the rear forward.

Where it goes wrong. Dating the vial when someone finally wonders about it. “It’s still clear.” A single-dose vial saved for later. Front-row-only sweeps.

The point to land: find it before the pharmacist does. An expired vial found by the Lead is housekeeping. The same vial found by a surveyor is a finding.

Demonstrates: states the multi-dose vial rule from memory, and finds planted expired stock during a walk.

Handout D-14 is the quick reference.

Topic 6 · Labeling and pre-drawn medications

Why this exists. The person who draws a medication is not always the person who gives it, and the moment a syringe leaves the hand that drew it, the label is the only identity it has. This is the topic where a paperwork habit is actually a patient-safety control wearing work clothes.

What to teach. Four things, on everything, every time: drug, strength, beyond-use time, and who drew it. Including the syringe that will be used in ninety seconds, because the ninety-second syringe is the dangerous one: it is the one nobody labels, and it is the one sitting on the counter when the phone rings.

An unlabeled syringe is an unidentifiable syringe, and an unidentifiable syringe is discarded, not sniffed, not remembered, not vouched for. Nobody can identify a clear liquid by confidence, and on a sterile field the same rule holds, where it is also the finding every accreditor cites.

What a label has to carry. The perioperative standard is specific, and it is the one most surgery centers are cited against. Anything transferred out of its original packaging into another container, on or off the sterile field, carries:

Element	Note
Medication or solution name	Full name, no abbreviations
Strength or concentration	With the unit of measure spelled out
Amount, where the container does not make it obvious	
Diluent name and volume, where anything was mixed	The diluent is part of the identity, not a detail
Expiration date, where it will not be used within 24 hours	
Expiration time, where it expires in under 24 hours	This is the one propofol makes real

Medication containers means syringes, medicine cups, and basins, not just syringes. The label goes on when the transfer happens, not when the task ends.

The one exception, and how narrow it is. A medication obtained, taken directly to the patient, and administered with no break in the process does not require a label. Read “no break” literally: no setting it down, no answering a question, no turning to another task. Any interruption ends the exception, and the safest teaching is that the exception exists but you should not plan around it.

Two people verify when the preparer is not the administrator. Verbally and visually, against the original container, before it is used. Keep the original containers available for reference until the procedure ends, because a question about what is in a syringe is answerable only while the vial it came from still exists.

Where the names are confusable, the label carries that too. Tall man lettering from the facility’s look-alike list in 6e goes on the label, not just on the shelf.

The habit that makes it stick: the label goes on before the hands move to the next task. Label, then move, every time, until it is not a decision anymore. Habits survive busy days. Decisions do not.

Teach it where drawing happens. Have the learner prepare and label under called-out time pressure.

The pass is the label completed before the hands move on, not the label completed eventually.

Where it goes wrong. The ninety-second exception. Labeling after the second item is drawn. Initials-only labels nobody else can read. Trusting syringe size or position as memory.

The point to land: an unlabeled syringe is an unidentifiable syringe, and the person who drew it is not always the person who gives it.

Demonstrates: labels correctly under time pressure, and can articulate why the ninety-second exception is the dangerous one.

Handout D-15 is the poster.

Topic 7 · Diversion awareness

Why this exists. A nurse or provider with a substance problem is a clinician in trouble, and a building where nobody notices leaves them in it until something irreversible happens, to them or to a patient. This topic protects colleagues first and inventory second, and if it cannot be taught in that order it should not be taught at all.

What to teach. The patterns worth noticing, plainly, at the level of records and rhythms rather than of people: waste consistently unwitnessed or always with the same witness. Quantities that do not fit the case. One person recording far more waste than their peers. Discrepancies that cluster around one shift, person, or location. Records completed late, in batches, after the fact. Sign-outs with no matching administration or waste. Volunteering for the drug keys, every time.

What noticing is and is not. Noticing is handing a pattern to the people whose job it is to look. It is not deciding anything, diagnosing anything, or accusing anyone, and uncertainty is enough: nobody is required to be sure, and the facility's process keeps it confidential.

The mechanics of reporting, taught concretely: tell the pharmacist and the DON what you observed, facts and dates, not theories. That is the whole act. What happens next belongs to leadership and the facility's process, not to the person who noticed.

What not to do, named because each one feels reasonable: do not confront the colleague. Do not investigate. Do not watch and wait for more proof. Do not discuss it at the station. Each of those makes it worse for everyone, including the colleague.

Teach it seriously and unhurried. Ten minutes minimum, framed exactly as the handout frames it. This topic taught badly, as a hunt, produces a unit that reports nothing and trusts less.

> PROGRAM **Diversion Prevention** · Owner: the pharmacist designs and reads it; the facility acts on it · Cycle: every count and every waste, sampling at each visit, pattern review each period · Artifacts: the investigation record, the root cause worksheet, and the pattern report to leadership · Measure: time from discovery to report, and time from report to a documented facility decision

Demonstrates: names four red flags and states exactly who they would tell and how.

Handout D-16 is the card, framed the same way.

Topic 8 · Discrepancy response

Why this exists. The minutes after a count fails to match are the most consequential minutes in this entire curriculum, and the untrained instinct in those minutes is precisely wrong. People fix things. Here, fixing is the damage.

What to teach. Three things, in order, and nothing else. Do not alter anything: not the log, not the count, not even to help, not even if you can see exactly what went wrong. Write down what you observed, exactly, now: what you counted, what the record says, when, where, who was present. Notify the pharmacist and the PIC immediately, both of them, not at the end of the shift and not after checking with a colleague first.

Two careful counts are allowed before the call. Recounting until the number cooperates is not, because the fifth count that finally matches proves nothing except persistence.

Why the do-not-alter rule is absolute. A corrected record destroys the evidence of what happened and makes an honest error look like concealment. The record as found is what protects the person who found it, and the sequence rule from the pharmacist's own training is the same rule here: document first, explain after.

What happens next, so the machine being fed is not frightening: the pharmacist opens an investigation record, establishes the window and the access list, and works the cause. Most variances resolve to documentation error. The person who found and escalated it is the system working, and the training says so in those words: you are not in trouble for finding it, and unsure counts.

Teach it with a staged mismatch. "You count 44. The record says 46. Go." The three steps, in order, unprompted, is the pass.

Where it goes wrong. Recounting until it matches. Fixing the math. Deferring to end of shift. Telling a buddy first.

The point to land: the instinct to "fix" a count is the single most damaging thing anyone can do here, and it is an instinct, not a decision, which is why it is rehearsed rather than merely explained.

Demonstrates: given a count that does not match, does the right three things in the right order.

Handout D-17 goes on the wall where the count happens, beside the daily count sheet, Form C-28.

Topic 9 · Working with the pharmacist

Why this exists. The visit goes twice as far when the facility side of it is prepared, and the Lead is the facility side of it. A pharmacist who spends the first half hour finding records is a pharmacist who is not teaching, reviewing, or fixing anything.

What to teach. The pull list, item by item: controlled substance logs since the last visit and the verification queue status. Temperature logs with corrective actions visible. Cart and box logs, with any seal events. Open findings, with the evidence gathered for the ones the facility owns. Incidents since the last visit. New hires and their training status. Anything expiring inside ninety days. Keys and access for the areas the visit will enter.

And the Lead's own list, which is the most valuable item on the pull list: the things that bothered you since last time. A drawer that sticks. A workaround someone invented. A question nobody could answer. A near miss that resolved itself. Bring it to the debrief unprompted, because the pharmacist asks leadership what changed, and the Lead is the person who actually knows.

Do not clean up for the visit. Tidying the truth before the pharmacist arrives hides exactly what the visit exists to find, and a workaround removed for a day comes back on the second shift. The visit is not an inspection to pass. It is the mechanism that fixes things.

Between visits, the two channels: the escalation list for the things that cannot wait, and the consultation log for the questions that change practice. The direct line exists to be used, and a Lead who waits three days twice will stop asking, which is the failure the role exists to prevent.

Teach it as a rehearsal. "The pharmacist is here Thursday. Show me what you get ready." The pull list produced without prompting, own list included, is the pass.

Where it goes wrong. Cleaning up. Waiting to be asked. Routing everything through administration. An empty own-list, visit after visit, which means either a perfect facility or a Lead who stopped looking.

If you disagree with the pharmacist. Say so, at the time, and say why. A finding built on a fraction of the week can be wrong, and the person who was there on the days the pharmacist was not is often the one who knows it. Bring what you know: what actually happened, who was there, and what the record shows. A pharmacist working to this standard will either correct the finding or explain why it stands, and either answer is a real one. If a disagreement cannot be resolved between you, it goes to the same place any other unresolved question goes, which is your own leadership. What should never happen is quiet disagreement, because a finding nobody argued with and nobody believes is a finding nobody will close.

Demonstrates: prepares for a visit without prompting.

Handout D-18 is the list.

Topic 10 · Survey readiness

Why this exists. A surveyor’s medication questions are not a quiz about regulations. They are a probe of whether the system exists and whether the people in it can operate it. Staff who understand that answer calmly, and calm, accurate, short answers are most of what survey readiness is.

What to teach. What surveyors actually do: ask the person in front of them, follow a medication or a patient through the building, and open the logs. The questions, practiced out loud until they are boring: where is your malignant hyperthermia cart. What do you do with an expired medication. How do you report a medication error. Show me your temperature log for last month. Who is your consultant pharmacist and when were they last here. What happens if a count does not match.

The three rules of answering. Short, true, and then stop talking. Retrieval is a full answer: “it’s in the log, let me show you” passes. “I don’t know, but I know exactly where it’s written” passes. A guess is the only failing answer, and so is a speech: an answer that keeps going volunteers findings nobody asked about.

Each role answers its own basics. A nurse answers what a nurse does. A surveyor who watches every question get relayed to one person has learned something true about the facility, and it is not flattering. The Lead is the backstop, not the ventriloquist.

The logistics, decided in advance: who escorts, who notifies the administrator, and the administrator notifies the pharmacist immediately, per the escalation table. If a surveyor is in the building, the pharmacist’s phone gets answered.

Teach it as rapid fire. The six questions, cold, out loud, with the facility’s specifics filled in. Then one curveball per person, because the real survey will not use the script.

Where it goes wrong. Guessing. Over-answering. “We always” and “we never,” which are promises no log supports. Fetching the Lead for every question.

The point to land: a confident, accurate, short answer is the goal. Nobody expects a nurse to quote a regulation.

Demonstrates: answers all six without hedging.

Handout D-19 carries the model answers.

Topic 11 · The anesthesia box

Why this exists. The box issued to anesthesia for the day’s cases holds more scheduled drug than every other location a nurse touches, and it moves. Custody that moves is custody that gets lost on paper long before anything is lost in fact. This topic makes the loop reflexive: issue, custody, reconcile, return, restock, every case, every day.

What to teach. The box is a location, not a convenience. It leaves the safe on a record and comes back on one. Between those two moments it is either in the provider’s direct control or locked, and at the end of every case two people prove the arithmetic before the room turns over.

The reconciliation, step by step. At case end, before the provider leaves and before the next case where practicable:

1. Bring the box’s issue record and the case’s sign-out together; the reconciliation is against the record, not against memory.
2. Count line by line: for each drug, issued equals administered plus wasted plus returned. Say the line out loud; arithmetic done silently is arithmetic done approximately.
3. Waste identified during the count is witnessed per Topic 2, at the moment, into the receptacle, never set aside for later.
4. Two people sign: the provider, and a second authorized person. The second counter is the control, and reconciling alone is a pattern that turns up repeatedly in diversion cases.
5. A mismatch stops the loop: secure the box, recount once, and if it stands, it is a discrepancy under Topic 8, reported now, worked today.
6. Return the box to the safe the same day, record the return, restock to par, and record the restock, so tomorrow starts from a known state.

Teach it at the cabinet. Stage a box with a deliberate one-unit short. Two learners run the reconciliation out loud, hit the mismatch, and practise the stop: secure, recount, report. The learner who wants to “just check the sharps bin first” gets the correction that matters: looking for the drug before securing the box is how evidence and custody both degrade.

Where it goes wrong. The box that floats all day without a formal issue. Several cases reconciled from memory at the end of the day. The provider who signs both lines. The restock done from a pocket count. The Lead’s job is to make each of these socially impossible, which is easier than making them procedurally impossible.

The point to land: the loop protects the provider most of all, because a clean chain is the only thing that turns “where did it go” into a records question instead of a people question.

What good looks like. The reconciliation reads from the record, so the arithmetic is already on the screen and the two people are verifying it rather than reconstructing it.

```
TOM MMS   TRAY  >  CASE-END RECONCILIATION
-----------------------------------------------------------
TRAY 2      CASE 4      PROVIDER  Dr. A. Vance
-----------------------------------------------------------
DRUG                ISSUED  ADMIN  WASTED  RETURN  STATUS
Midazolam 2 mg         2      1       1       0    balanced
Fentanyl 100 mcg       2      1       1       0    balanced
Hydromorphone 1 mg     1      0       0       0    balanced
-----------------------------------------------------------
SECOND COUNTER   [ Select                            v ]
                 PIN  [ * * * * ]
-----------------------------------------------------------
[  CLOSE TRAY  ]        any mismatch opens a discrepancy
```

What to notice: every line is attached to the case it came from, so nothing has to be remembered at the end of a list of cases; the second counter authenticates rather than signs; and a mismatch does not produce a warning to be dismissed, it opens the discrepancy path from Topic 8.

Demonstrates: runs the six steps on a staged box, catches the short, stops correctly, and can say why the second counter exists.

In TOM MMS the box's day runs on the workflows this curriculum already teaches: the protocol pull issues against the case, witnessed waste carries its gate, and the case linkage keeps every line attached to the case it belongs to, so the reconciliation reads from the record instead of memory. Form C-38 is the paper version.

Competency record

Recorded per person, per topic, with a date. This is the same evidence the facility needs for its own staff competency file, so the program produces documentation the facility was going to have to produce anyway.

Refresh annually. Train new hires on the same content when they start rather than waiting for the annual cycle, because a nurse hired in February should not learn the medication routine by watching whoever is nearest.

> **PROGRAM** **Facility Team Competency** · Owner: the Pharmacy Lead teaches; the pharmacist verifies by demonstration · Cycle: new hires trained before touching medications, refresh annually, competency confirmed at each pharmacist visit · Artifacts: the competency register, the per-topic check records, and the training handouts · Measure: share of current staff current by topic, and time from hire to first medication task

Record what the person can do, not what they attended. A signature on an attendance sheet is evidence of a room, not of a competency. Handout D-21 is the assessor's check script, per topic.

The escalation rule

The Lead runs the routine. They do not make pharmacist judgments. Name what escalates, in writing, posted where the Lead works:

- Any controlled substance discrepancy, of any size
- Any suspected diversion

- Any out-of-range excursion involving a temperature-sensitive drug
- Any expired stock found in an active location
- Any medication error or adverse reaction
- Anything the Lead is unsure about

Unsure is a valid reason to escalate. Say it in the training, in those words, and have the pharmacist say it too. A program that punishes uncertainty gets certainty that was manufactured, and manufactured certainty is how a real problem stays invisible until it is not. Post Handout D-20 beside this list, with the names filled in.

Supporting the Lead between visits

The role fails from isolation more often than from ignorance.

Give the Lead a direct line to the pharmacist rather than routing through administration. Answer quickly. A Lead who has waited three days for an answer twice will stop asking and start deciding, which is precisely the outcome the role was created to prevent.

3.4 The routine, in depth

Section 1.3 gives the shape. This is the routine itself, written so a Lead can be taught from it and a pharmacist can verify against it. Clock times and staffing assignments are deliberately absent. Centers set their own hours and decide who does what; the anchors below are events in the day, and which role carries each one is the facility's call.

The daily routine

Before the first patient. Everything here is done while the building is still quiet, because after the first case starts the schedule owns the day.

1. Controlled substance count at each storage location, two people where the facility requires it, against the running balance rather than against yesterday's memory. Topic 1 carries the procedure.
2. Refrigerator and freezer readings recorded for every unit, including the ones nobody uses often. Out of range triggers Topic 3's response at the moment it is found, not at the end of the day.
3. Cart and tray seals checked and recorded, with any broken or missing seal treated as an entry until proven otherwise.
4. Expirations spot-checked in the locations opened today, because the vial that expires this month is easier to catch now than at the point of care.

Between cases. The tempo is pull, give, close, inside the turnover gap. Sign-out at the point of care rather than reconstructed later, waste witnessed at the moment with the second person present, and the tray reconciled at case end per Topic 11. The one rule that protects all three: the record is made where the work happens, by the person who did it.

When deliveries arrive. Whoever owns receiving breaks off and runs the three-way match from section 5d against the order and the invoice before stock goes to the shelf. Controlled substances are entered into the perpetual inventory the same day they arrive.

After the last case. The opening in reverse, and it is the half most often skipped: closing counts, closing temperature readings, last wastes witnessed and recorded, restock to par recorded so tomorrow starts from a known state, and anything unresolved written down for the Lead rather than carried home in someone's head.

Where it succeeds. The routine is reflexive rather than remembered: new staff learn it by working beside someone who does it the same way every time, the counts happen on light days as reliably as on heavy ones, and no one has to decide whether today is a day for it. The strongest signal of a healthy routine is that staff can tell you what they do when the usual person is out.

Where it fails. The opening compressed into the first add-on case. The closing done from memory after the last patient leaves. The temperature log filled in for three days at once, in one pen, which a surveyor tends to recognize on sight. And the quiet day where nothing happened and nothing was recorded, which is the day that turns a variance into an unanswerable question.

The weekly and monthly rhythm

The Lead’s week has a shape worth naming, because a routine with no rhythm becomes a routine that only runs when someone remembers.

Interval	The work	Evidence it happened
Weekly	Verify the daily records are complete rather than merely present; walk one storage location fully; check the expiration horizon inside ninety days; confirm seal and count records have no gaps	Initialed weekly review line on the daily record
Before a pharmacist visit	Build the pull list from Topic 9, and write down what to raise: the near misses, the awkward questions, the things that felt off	The Lead’s own list, brought to the visit
Monthly	The refrigerator deep reconciliation from 3e; contents against the formulary in both directions; the month’s excursion ledger closed; the look-alike and high-alert lists checked against the shelf	Dated monthly reconciliation record
Quarterly	Full count of every location on rotation per 2i; competency currency reviewed for the team; policy changes since last quarter reflected in practice	Rotation log and competency register
Annually	Competency refresh for every person, the federal biennial confirmed and recorded, license and registration renewals checked against their dates	C-19 refresh dates, inventory record

The habit that separates a Lead from a keyholder is the written list. A Lead who arrives at the pharmacist visit with their own questions is running the routine; a Lead who only produces records when asked is holding keys to it.

Beyond the floor. No standard asks a facility staff member to prepare for a consultant’s visit. This one does, because the questions a Lead writes down during the weeks nobody was watching are the only route to the days the pharmacist cannot observe.

Between visits, the escalation line is the Lead’s spine. Any discrepancy of any size, any suspected diversion, any out-of-range excursion involving a temperature-sensitive drug, any expired stock in an active location, any medication error, and anything they are unsure about goes to the pharmacist the day it is found, in writing. Unsure is a valid reason to escalate, and a program that punishes uncertainty gets certainty that was manufactured.

In TOM MMS the daily routine is the Home screen’s opening and closing checks, the weekly and monthly work carries its own due dates, and the Lead’s list keeps the between-visit questions rather than a note that gets lost between Thursday and the visit.

3.5 When the routine breaks

The eleven topics cover the day as it usually runs. This section covers the day as it sometimes runs, and it exists because the moments that damage a record are almost never the ordinary ones. Post it where the Lead works. Teach two or three of these per session rather than all of them at once.

The rule underneath all of them. Do the safe thing for the patient first. Then make the record true, even if true is ugly. A record that says what actually happened, including that something went wrong and when it was noticed, is worth more than a tidy record that is partly invented. Nobody is ever in trouble in this program for writing down what happened.

Systems and infrastructure

The network drops. TOM MMS is installed as an app on the device and captures point-of-care entries when the connection drops and syncs them when it returns. A temperature reading keeps its capture time; a controlled-substance entry records the time the server accepts it unless a late entry is marked. Keep working. Do not switch to paper for a short outage, because two half-records are harder to reconcile than one complete one. When the connection returns, confirm that the day’s entries are present before the shift ends. That confirmation is the whole of the Lead’s job here.

The device is dead, lost, or locked out. This is a different failure from the network, and it is the one that puts you on paper. Use the Appendix C forms, kept where staff can reach them without asking anyone. Record the true event times as you go. When the system is available again, enter them as late entries with the real times, marked as entered late. Never backdate. A late entry honestly marked is a normal operational event. A record made to look contemporaneous is the thing an investigator disbelieves first, and it converts a small problem into a large one.

The power fails. Refrigeration has its own countdown and its own procedure in 3f. For the medication record, work on paper, keep the doors closed, and write the times down as they happen rather than reconstructing them afterward.

The cabinet or safe will not open. Do not force it and do not improvise a second store of drugs. Tell the Lead, who tells the pharmacist. If a patient needs a medication now, the facility’s own emergency access procedure governs and every entry into that path gets recorded at the time, with two people present wherever the procedure allows it.

Custody events

A dose is dropped, spilled, or broken before it reaches the patient. It still has to be accounted for. Waste it with a witness exactly as if it had been administered and partly wasted, and say plainly in the record what happened: a vial was dropped, a syringe was contaminated. Sweeping it into a sharps container without a witness is the single most common way a real count goes wrong for an entirely innocent reason.

A case is cancelled after the medication was pulled. The chain does not care why the case ended. What was issued has to be administered, wasted, or returned, and the return goes back on a record with the same discipline as the pull. A returned drug that nobody recorded is a drug the count says was given

to a patient who never existed.

The provider leaves without wasting. Do not waste it for them and do not sign as the witness to a waste you did not see. Secure the remainder, record that it is secured and by whom, and escalate to the Lead the same day. This is uncomfortable and it is exactly the situation the standard exists for.

No second person is available to witness. Do not proceed and do not record a witness who was not present. Secure the medication, note the time and the reason, and complete the waste when a witness is available, recording both times. If this happens more than rarely, it is a staffing pattern rather than an incident, and the Lead raises it as one.

A count does not match. Stop. Do not search for the drug first, do not adjust the record, and do not ask around informally. Secure the location, recount once with a second person, and if it still does not match, report it under Topic 8 the same day. Searching before securing degrades both the evidence and the custody.

Medications are found somewhere they should not be. A vial in a pocket, a syringe on a counter, stock in an unregistered drawer. Do not put it back into usable stock. Secure it separately, record where it was found and by whom, and escalate. It may be innocent, and it may be the first visible symptom of something else, and the way to keep both possibilities open is to preserve what you found rather than to tidy it.

Clinical urgency

A code or an emergency where documenting in the moment is impossible. Treat the patient. Nobody signs out midazolam during a resuscitation and this standard does not pretend otherwise. As soon as the patient is stable, one named person reconstructs the medication record from the code sheet and the people who were present, records the true event times, and marks it as a late entry. Do the reconstruction the same day while memory is intact, and do not spread it across several people, because a record assembled from four half-memories agrees with nothing.

A medication error reaches the patient. Clinical care first, always. Then tell the Lead and the treating provider immediately, keep the containers, the labels, and the packaging exactly as they are, and write what happened in plain factual language with no adjectives and no speculation about cause. Do not alter any existing entry. Section 1.2 governs what happens next: the question is what the system allowed, not who to blame.

The facility has to evacuate with medications out of their locations. Patient safety governs everything. If it is possible to secure the controlled stock on the way out, do it, and if it is not, note that too. Reconstruct the position as soon as it is safe, with two people, and record the whole sequence as one event including the gap. A documented gap is a finding. An undocumented gap is a mystery.

The pattern to teach

Every one of these resolves to the same four moves, and a Lead who can name them can handle a scenario this section never anticipated.

1. **Patient first.** Nothing in a record outranks the person in front of you.

2. **Secure before you search.** Whatever is left stays where it is, under control, until somebody with authority looks at it.
3. **Tell someone today.** The Lead, then the pharmacist. In writing. Unsure is a valid reason to escalate.
4. **Write what happened, at the true time, marked honestly.** Including the parts that are unflattering, and including the fact that you were writing it later.

In TOM MMS point-of-care entries are captured on the device when the connection drops and sync when it returns. A temperature reading keeps its capture time; a controlled-substance entry records the time the server accepts it unless a late entry is marked with the actual time. The late-entry flag marks a record made after the fact without hiding it, and an amendment preserves the original alongside the correction rather than replacing it. None of that decides what should be recorded. This section does.

PART FOUR

Follow-Through

PART 4 · FOLLOW-THROUGH

What this part is for. A finding that nobody closes is a sentence in a report. This part turns findings into obligations: every one gets an owner, a due date, and documented evidence that it closed, or an explicit record that the facility accepted the risk and why.

Why it exists as its own part. It is the part a paper program loses first, and it loses it quietly. Nobody decides to stop closing findings. The report gets written, the visit ends, and the next visit re-discovers the same thing with a new date on it.

Inside: the problem this part solves, the rule, the states a finding moves through, accepted risk, corrective action versus action item, what the pharmacist owes each visit, and what good looks like.

4.1 The problem this part solves

A visit report is a photograph. Follow-through is what turns a series of photographs into a trend.

The failure is easy to recognize once named. A pharmacist documents a finding. The report goes to the administrator. The administrator is busy. Three months later the pharmacist returns, finds the same thing, documents it again, and both parties experience this as the program working. It is not working. It is recording.

Follow-through is the layer that makes a finding an obligation instead of an observation.

4.2 The rule

Every finding has an owner, a due date, and documented evidence of closure.

Three parts, and all three are load-bearing.

An owner is a named person or a specific role, never “staff” and never “the facility.” Work assigned to everyone is assigned to no one. If the pharmacist cannot name an owner before leaving, the finding is not ready and the conversation that produces the owner has not happened yet.

A due date is proportional to severity and agreed rather than imposed. A date the facility did not agree to is a date the pharmacist invented, and it will pass. Agreement takes ninety seconds at the debrief and it is the difference between a plan and a wish.

Evidence of closure is the part almost everyone skips. A finding is not closed because someone said it was closed. It is closed when there is something to look at: a corrected log, a photograph, a completed training record, a signed policy, a recount. The evidence is attached to the finding and it stays attached.

4.3 States a finding moves through

State	Meaning
Open	Documented, owner assigned, due date set. Nothing done yet.
In progress	Work started, evidence not yet complete.
Evidence submitted	The facility says it is done and has attached something. Not yet closed.
Closed	The pharmacist reviewed the evidence and accepted it.
Reopened	Closed previously, observed again. Tracked as recurrence, not as a new finding.
Accepted risk	The facility has declined to correct it. Documented with who decided, when, and their stated reason.

Figure 2 · The finding lifecycle

```
OPEN > IN PROGRESS > EVIDENCE SUBMITTED > CLOSED
                          (only a pharmacist closes)
                                        |
                                  observed again
                                        v
                                    REOPENED
                            (counted as recurrence, not as new)

ACCEPTED RISK: a documented exit available at any state.
Decision-maker named, reason in their words, reviewed on a date.
```

[Figure for design render. The text version is the spec.]

Two of these states matter more than they look.

Only a pharmacist closes a finding. The facility submits evidence. The pharmacist accepts it. A self-closing finding is an unverified claim wearing the word closed, and the whole program depends on that word meaning something.

Reopened is not a new finding. If the same gap returns, it is a recurrence and it is counted as one. Recurrence is the most useful signal in the program, because it distinguishes a facility with a documentation problem from a facility with a systems problem. Filing a recurrence as new hides exactly the pattern you most need to see.

4.4 Accepted risk, and why it belongs here

Sometimes a facility will not do the thing. The equipment is not in the budget, the physician owner disagrees, the change is genuinely impractical this quarter.

Do not delete the finding, do not soften it, and do not carry it open forever so it silently pollutes every count.

Record it as accepted risk with the decision-maker’s name, the date, and their stated reason in their words. Then it appears in the quarterly review as what it is: a known, documented, deliberate exposure with a name attached.

This protects everyone. It protects the facility, because a documented decision is defensible in a way that an undocumented gap is not. It protects the pharmacist, because the recommendation exists in writing. And it converts an argument into a record, which is usually the fastest way to end the argument.

An undocumented exception is a finding. A documented one is a decision.

4.5 Corrective action versus action item

Two instruments, and using the wrong one is the most common process error in follow-through.

An action item is a task. Something is missing, incomplete, or out of place, and doing the task fixes it. Restock the expired vial. Complete the missing log entries. Update the policy to the current version.

A corrective and preventive action is a systems change. The same problem has happened more than once, or it is severe enough that recurrence is unacceptable. A CAPA asks why it happened and changes something so it stops happening.

The test: if fixing this exact instance means it cannot recur, it is an action item. If fixing this instance leaves the cause intact, it is a CAPA.

Rule: the second occurrence of any finding is a CAPA, not a second action item. If you have written the same action item twice, the task was never the problem.

4.6 What the pharmacist owes each visit

Before the visit, aging matters more than volume. Review open findings, note what is overdue, and be ready to ask about it by name.

During the visit, every open finding gets addressed out loud. Not comprehensively, but each one gets a sentence. Silence on an open finding tells the facility it did not matter.

At the debrief, closures are confirmed against evidence, new findings get owners and agreed dates, and anything overdue gets a direct question about why.

After the visit, and same day, the record is submitted with every state accurate.

4.7 What good looks like

Not zero findings. A facility with zero findings is a facility where nobody looked hard.

What good looks like:

- Findings close on or near their due date more often than not
- Recurrences are rare, and each has a CAPA attached
- Critical findings close fast, in days rather than visits
- Accepted risks are few, named, and reviewed rather than accumulating
- The open list is shorter than it was two quarters ago, or the same length because the program keeps finding new things at a stable rate

That last one is worth sitting with. A mature program still generates findings. It generates different findings. A program producing the same ten findings every visit is not a program at all, which is exactly the condition this part exists to end.

Running this without software

This is the layer where a paper program dies first, and it dies quietly.

Look at what follow-through actually requires between visits. Someone carries the open list forward. Someone compares this visit’s findings against the last several to notice a recurrence, which is a signal no single visit can produce in the program and the one that is invisible unless you go looking. Someone keeps the closure evidence somewhere it can still be found a year from now. Someone assembles the trend.

A spreadsheet does all of that, right up until the week you are busy. Then a finding does not get carried, a recurrence gets filed as new, and the program degrades without anyone noticing, because nothing about a spreadsheet announces that it has stopped being maintained.

TOM MMS was built for this part specifically. A finding cannot exist without an owner and a date, because they are fields rather than discipline. Recurrence is detected rather than remembered. Evidence attaches to the finding and stays attached. The trend assembles from the record instead of being compiled.

You can run this standard without it. You will spend the difference in evenings.

PART FIVE

Expertise

PART 5 · EXPERTISE

What this part is for. The first four parts can be run by a disciplined process. This part is the judgment that a process cannot supply: what to prioritise, what a pattern means, what to say to an administrator, and what to do when the answer is not in any rule.

Its edges are stated deliberately. A consultant pharmacist is not the facility’s operator, not its HR function, and not the decider of its compliance. The value in this part is real precisely because those limits are drawn, and the final section draws them in plain language.

Inside: what this part is for, the five functions, between-visit access, working with the facility team, what the administrator gets, engagement models, running a portfolio including scheduling, routing, and scaling past yourself, what to do when an engagement gets hard, and the limits of the role.

5.1 What this part is for

The first three layers are structure. A standard tells you what to look at, a trained team can run it, and follow-through makes findings close. Run well, that produces a facility that is organized.

It does not produce a facility that is safe. Structure cannot tell you that the count reconciled but the pattern behind it is wrong. It cannot tell you which of eleven open findings is the one that will hurt someone. It cannot answer the question a director asks at four in the afternoon on a Tuesday.

Part 5 is the pharmacist. Specifically, it is pharmacist judgment, clinical and commercial, made available on the facility’s timeline rather than only on the visit schedule.

5.2 The five functions

Review. Reading the record for what it means rather than whether it is complete. Layers 1 through 3 confirm a temperature log exists and is filled in. Part 5 notices that the same unit has drifted toward the top of range for six weeks and says the compressor is dying before the vaccine is lost.

Prioritization. A facility with fourteen open findings does not have fourteen problems, it has two problems and twelve chores. Ranking them is not a calculation and cannot be automated, because it depends on the case mix, the staffing, the survey window, and what happened here last year.

Coaching. Teaching the team in the moment. The training layer covers the routine. Coaching covers the thing that just happened, with the person it happened to, while it is still fresh. Most of the durable learning in a pharmacy program happens this way.

Access. Being reachable. A director who can ask a pharmacist a question on the day the question arises makes a different decision than a director who waits, or guesses, or asks a colleague.

Business judgment. The fifth function, and the one that separates a consultant from an inspector.

An ASC is a business with thin margins, and drugs are a line item that almost nobody in the building can read properly. The pharmacist can. Purchasing and contracting, formulary economics, waste as a cost rather than as a compliance item, par levels against actual use rather than against habit, and what a proposed clinical change does to spend per case.

TOM pharmacists are PharmD, and each carries an MBA or real business management experience. That is deliberate. An administrator who has a compliance problem calls a consultant once a quarter. An administrator who has someone who can also explain where the drug spend goes calls them when something changes.

Both halves, or the relationship stays shallow. A pharmacist who only talks compliance becomes the person who brings problems. A pharmacist who only talks cost is a purchasing consultant. The combination is what makes the visit something the facility looks forward to rather than tolerates.

5.3 What between-visit access actually means

State it concretely or it becomes a marketing line.

Committed. A response within one business day to any question, and same-day for anything involving controlled substances, a suspected diversion, a patient safety concern, or an active survey. If a surveyor is in the building, the phone gets answered.

Not committed. Being on call around the clock, and standing in for the facility's own clinical decision-making. A consultant pharmacist advises. The facility decides and the facility owns its compliance.

Documented. Anything advised between visits that changes what the facility does is recorded, so the advice is part of the record and not part of a conversation nobody can reconstruct. A verbal recommendation that later matters and exists nowhere is the same defect as an undocumented finding. Form C-29 is the log.

5.4 Working with the facility team

The program has one pharmacist and many counterparts. Each of them needs something different from you, each of them knows something the others do not, and the most common failure in consultant practice is talking to only one.

5.4.1 Who you are actually working with

The administrator or executive director. Owns the budget, the vendor relationships, and the survey outcome. Wants to know risk, cost, and whether anything is going to embarrass them. Speaks in dollars and in survey exposure.

What they need from you: a short, honest picture of where the facility stands, with the two things that matter most named. Never a list of eleven items with no ranking.

What they know that you do not: what is changing. Ownership, new service lines, staffing plans, the survey window, and which vendor contracts are being renegotiated. All of it affects pharmacy and none of it will be volunteered unless you ask.

The director of nursing. Owns the staff who touch every medication in the building. Usually the most valuable relationship in the facility, and often the most under-used by consultants.

What they need from you: findings framed as something their team can act on, not as a critique of their team. And warning. A DON who learns of a finding from the administrator rather than from you will stop helping you, quietly and permanently.

What they know that you do not: who is struggling, who is new, where the workarounds are, and which policies staff find impractical. This is where the real state of the medication system lives.

The Pharmacy Lead. Runs the daily routine. Your primary operational counterpart and the person who determines whether anything you recommend survives past your visit.

What they need from you: answers, quickly, and the sense that the role has backing. Also protection: a Lead who escalates something and gets no support will stop escalating.

What they know that you do not: everything about how the routine actually runs, as opposed to how it is documented.

The nurses. The people who open the cabinet, draw the syringe, and record the waste.

What they need from you: to not be treated as suspects, and to be taught rather than corrected. Also to be asked, because they are asked least and know most.

What they know that you do not: what actually happens at the start of the day when the first case is late and the drug room is locked.

The anesthesia professionals. A parallel medication system, largely self-contained, and where controlled substance volume concentrates. Often the hardest relationship and frequently avoided, which is exactly why it is worth building.

What they need from you: respect for clinical autonomy, and a clear distinction between how a drug is

used, which is theirs, and how it is documented and accounted for, which is the facility's obligation and yours to review. And a colleague: bring the pharmacology when the team is choosing, because the pharmacist is part of the decision team, not a spectator to it.

What they know that you do not: why the workflow is the way it is, and what would actually work instead.

The medical director and governing body. Own the policies and the quality program. You will usually reach them through the summary rather than in person. Write it so it can be read by a physician who is not a pharmacist.

The PIC or responsible individual, where the state requires one. Confirm who it is, that they know they are it, and that the designation matches the manual. A designation nobody has told the designee about is common and is a finding.

5.4.2 The visit, as a sequence of conversations

Before you arrive. A short message to the Pharmacy Lead: when you are coming, what you will need pulled, and anything you want set aside. This costs two minutes and buys twenty on site, because the records exist when you get there rather than being found while you wait.

On arrival. Director or DON first, always. Three questions: what changed, has anything worried you, and is there anything you want me to look at. The second question produces more findings than any checklist item in this document.

During the visit. Walk with the Pharmacy Lead where practical. You are reviewing and they are learning simultaneously, and a correction delivered at the cabinet, in the moment, sticks in a way a line in a report never does.

Talk to at least one nurse who is not the Lead, and ask them to show you something rather than tell you. Phase 7 explains why this is worth the minutes it costs.

Critical findings, immediately. Not at the debrief. To the DON or administrator, in person, when you find it.

The debrief. Director or DON, with the Pharmacy Lead present. The Lead's presence is not a courtesy. They will own most of what is agreed, and a person who was in the room when a date was set treats it differently from a person who received it afterward.

Before leaving. Next visit scheduled. Owners and dates agreed out loud.

5.4.3 Between visits

The Pharmacy Lead has a direct line to you. Not routed through administration. A Lead who waits three days for an answer twice will stop asking and start deciding, which is exactly what the role exists to prevent.

Response commitments, stated so they can be held to:

- Same day for anything involving controlled substances, suspected diversion, a patient safety concern, or an active survey

- One business day for everything else
- If a surveyor is in the building, the phone gets answered

Document anything that changes practice, per the rule in 5.3. Advice given between visits that alters what the facility does belongs in the same place the findings live, not in a text message.

Proactive contact matters more than it looks. A short note when a recall lands, when a shortage hits a drug on their formulary, or when a registration is approaching expiry is the cheapest trust-building available and is the thing facilities remember at renewal.

5.4.4 The escalation path, written down

Post it where the Lead works. Everyone should be able to answer “who do I call” without thinking.

Situation	Who acts first	Who is told, and when
Controlled substance discrepancy	Lead documents, does not alter	Pharmacist and PIC, immediately
Suspected diversion	Lead documents observation only	Pharmacist and DON, immediately. Not the colleague.
Temperature excursion	Lead executes corrective action	Pharmacist same day if a temperature-sensitive drug is affected
Expired stock in an active location	Lead removes and quarantines	Pharmacist at next contact; immediately if it was administered
Medication error or adverse reaction	Facility process; physician notified	Pharmacist same day
Survey or inspector arrives	Administrator	Pharmacist immediately
Lead is unsure	Lead escalates	Pharmacist. Uncertainty is sufficient reason.

Handout D-20 is this table as a printable page, with lines for the names.

5.4.5 Failure modes

Named because each one is common and each one is invisible to the person doing it.

Talking only to the administrator. Produces a program that looks good in a summary and changes nothing on the floor, because the people who would have to change something were never in the conversation.

Going around the Pharmacy Lead. Escalating something to the DON that the Lead could have handled undermines the role you created. If the Lead is the problem, that is a conversation with the DON about the role, not a habit of bypassing it.

Treating nurses as suspects, or arriving as the compliance police. Both produce the same result and it is covered at length in Module 7: a facility that shows you what it wants shown. Named here because it is a failure of the working relationship rather than of technique, and because nobody doing it

thinks they are.

Avoiding anesthesia. The highest controlled substance volume in the building with the thinnest record, left unexamined because the conversation is uncomfortable.

Absorbing the facility's work. A consultant who closes findings themselves because it is faster has created a facility that cannot close findings. The job is to make the facility capable, not to be the capability.

5.4.6 Boundaries, and how to hold them

You will be asked to cross these by decent people under real pressure. Decide the answers now.

You are not the facility's HR function. The moment a finding points at an individual, it belongs to facility leadership, and possibly counsel and law enforcement. Document the pattern, hand it over, stay available. Do not interview anyone as an investigator.

You do not make clinical decisions. You advise. The facility decides and the facility owns its compliance.

You do not sign what you did not review. No exceptions, no matter who asks or how reasonable the reason sounds.

You do not backdate. Ever. A record created later is recorded as created later.

Practise the refusal sentence in advance, because inventing it in the moment is how people say yes. "I cannot record it that way, and here is what I can do instead." Then offer the alternative, because a no with a path forward is accepted and a bare no is resented.

Anesthesia is a different relationship

The document has now asked a great deal of anesthesia: a tray reconciled by two people at case end, waste witnessed at the moment, a rescue stock decided jointly, paralytics segregated, and a record that closes the same day. All of that is reasonable and none of it happens because a pharmacist wrote it down. This subsection is about why, and what to do instead.

Understand the structure before the conversation. In most ambulatory centers, anesthesia is not the facility's staff. It is frequently an independent group under contract, sometimes several individuals, sometimes a staffing company, and its members may work at three other buildings this week with three other sets of expectations. They do not report to the administrator in the way a nurse does, and in some arrangements the administrator has no practical authority over their practice at all. A pharmacist who assumes otherwise makes a request that has nowhere to land.

They are also the highest-volume handlers of controlled substances in the building, which means almost every custody control in this document touches their day more than anyone else's. That asymmetry is worth saying out loud to yourself before you propose anything: you are asking the busiest people in the building to absorb the most change, and you have no authority to require it.

They have their own professional standards, and they predate yours. Anesthesia has society guidance on drug handling, on the rescue drugs this document discusses, and on practice in the operating

room. Arriving as though none of that exists is the fastest way to be discounted. Ask what their society says before offering what this standard says, because most of the time they agree, and the places they agree are where you should start.

What actually works.

- **Bring the record, not the rule.** “Three of the last twenty cases have a tray that closed the next morning” starts a conversation. “The standard requires same-day closure” ends one.
- **Ask what would make it easier before proposing what they should do.** The answer is usually physical: where the tray lives, how far the waste receptacle is, whether a second person is anywhere nearby at the end of a list. Several of the hardest compliance problems in this document are solved by moving furniture.
- **Never surprise them in front of anyone.** Not in a meeting, not in a report the administrator reads first. A finding that touches anesthesia practice is raised with them before it is raised about them, and section 1.2 is the reason.
- **Route practice patterns through the medical director**, as 2h says. Not because the pharmacist is avoiding the conversation, but because that is who holds the relationship and, in many arrangements, the contract.
- **Give them something.** The rescue stock decision in 4e, the antidote work in 9.6, a shortage flagged before it bites, a formulation change caught early. A pharmacist who has only ever asked anesthesia for something has not yet started the relationship.

When anesthesia declines. It happens, and it is usually not obstinance. It is a group that has been asked for the same thing at four buildings in four different formats, or one that has been burned by a consultant who reported them rather than talked to them. Document what you asked, what you were told, and what the residual risk is, then raise it once through the medical director with the risk stated plainly rather than repeated. After that it is the facility’s decision and 4.4’s accepted-risk path is where it lives. What you do not do is escalate repeatedly, work around them, or write it up in a way that reads as a complaint.

The thing worth remembering. Almost every anesthesia provider wants a clean controlled substance record more than the facility does, because when a count does not reconcile, they are the person standing closest to it. The chain of custody in 1.4 protects them more than it protects anyone else in the building, and saying that early, honestly, changes the conversation more than any citation will.

5.5 What the administrator gets

An administrator who hires a consultant pharmacist is not buying visits. They are buying back two things they never have enough of: time, and sleep. This section is the whole-facility ledger of what the role returns, written so an administrator can read it directly, and so a pharmacist can say it out loud without overclaiming.

The honest frame first. The pharmacist is not the administrator's operator. Staffing models, OR throughput, payer strategy, and capital planning belong to leadership, and a pharmacist who wanders into them uninvited spends credibility they need for the medication layer. The value below is real precisely because its edges are.

Administrator's domain	What the pharmacist contributes	Where this document carries it
QAPI program	The complete medication component: six trended indicators with denominators, a quarterly two-sentence-per-indicator feed, and one documented improvement project a year	6.5, 6.6, Forms C-33 and C-34
Survey readiness	A medication layer that answers on demand: staff drilled on the questions surveyors actually ask, records that retrieve in seconds, and a mock-survey option before the accreditor arrives	Part 1, Topic 10, Form C-36, the survey posture in Module 9
Incidents and root cause	Investigation discipline for the med-room events that frighten administrators most: variances worked to cause, corrective action separated from action items, and the do-not-alter culture that keeps an honest error from reading as concealment	4.5, Module 5, Topic 8, Form C-35
Board and leadership reporting	A one-page periodic summary written in administrator language, assembled from the record rather than memory, ready for the quality committee packet unedited	6.4, Module 8, Form C-37
The numbers	Five figures nobody else in the building can produce: spend per case, waste share, top movers, par against use, and what is coming, each with its denominator and its sentence	Module 8, Handout D-8
Supply and formulary economics	Purchasing observations tied to clinical reality, renewal flags before	5.2, Module 9

	clinical reality: renewal flags before procurement asks, formulation changes before a policy breaks, par levels against actual use	
Staff capability	A trained Pharmacy Lead running the daily routine, nurses who can answer a surveyor without fetching anyone, and competency records that prove it	3.1, the topics, Form C-15
Risk that never surfaces	The anticipatory layer: expirations caught at ninety days, shortage and recall feeds read against this formulary, tomorrow’s citation written as today’s informational finding with an owner	Module 9, Handout D-9
Infection-prevention interface	The medication half of the IP program: single-dose discipline, beyond-use dating, labeling at the point of care, and the storage conditions record	Topics 5 and 6, Phase 3
Time itself	Visits that run to a standard instead of a mood, findings that close instead of recur, and a debrief that ends with what is coming rather than what went wrong	Layers 1 and 3, the cycle

Choosing a consultant pharmacist

Administrators hire this role rarely, often once, and usually with no basis for comparison. These are the questions worth asking, and they are printed here deliberately: a pharmacist who is uncomfortable being asked them is answering the question.

1. **What does a visit include, and what does it produce?** A written report with findings that carry owners and dates, or a verbal reassurance. Ask to see a redacted example.
2. **What happens between visits?** Access to a pharmacist for a same-day question is most of the value of the role, and the answer should be a commitment rather than a courtesy.
3. **Who trains our staff, and how is that evidenced?** If the answer does not include a record you can produce at survey, the training does not exist as far as a surveyor is concerned.
4. **How do findings close?** Ask specifically what happens to a finding that is still open at the next visit, because that answer describes whether you are buying a program or a series of reports.
5. **What do you need from us?** A pharmacist who needs nothing is not going to change anything. Expect to hear about a named Lead, protected time, and access.
6. **What will you tell me that I will not want to hear?** The most useful question on this list.
7. **What happens if you are unavailable, or if we part ways?** Coverage, and a handover that leaves the facility’s records usable by the next person.

8. **Licence, insurance, and the agreement.** Current licensure, professional liability coverage appropriate to consultant practice, a written scope, and a business associate agreement where protected health information is involved.

Two answers that should give you pause. A fee that varies with what is found, in either direction, which compromises the independence the role exists for. And a promise that you will pass your next survey, which nobody can promise and which tells you how the rest of the answers were constructed.

Knowing whether it is working

The honest measures are visible to an administrator without pharmacy knowledge, and they are mostly about movement rather than volume.

- **Findings close.** The open count falls or holds, and the oldest open item is not older than it was last period. A rising count of aging findings is the clearest signal a program has stalled, regardless of how thorough the reports look.
- **Repeat findings become rare.** The same issue recurring visit after visit means corrective action is not happening, per 4.5.
- **Your staff can answer questions.** Ask a nurse where the last cart check is recorded. The answer, and the speed of it, tells you more than any report.
- **You hear about problems before you would have found them.** A program that only reports good news is not reporting.
- **The summary is readable and it changes.** A leadership summary that says the same thing every period is a template, not an assessment.
- **Surveys get less eventful over time**, which is the outcome, though it is the slowest of these to observe.

And the question to ask yourself once a year: if this pharmacist stopped coming tomorrow, how long until it showed? If the answer is immediately, the program depends on a person rather than on a system, and 3.2’s deputy and Part 3’s curriculum are the fix.

The sentence version, for the hallway: the pharmacist owns the layer of the building that surveyors read first and administrators see last, and runs it so the administrator never has to think about it between reports.

What this section is for. Two audiences. The administrator deciding whether the role is worth the fee reads the table and the edges. The pharmacist who cannot yet say what they are worth reads it until they can, because Module 8’s rule applies to the role itself: never a value claim without its evidence, and every row above names where the evidence lives.

5.6 Engagement models

Three ways a facility gets Part 5. Layers 1 through 3 are identical in all three, which is the point. The standard does not change based on who is paying whom.

Model A · Keep your current pharmacist

The facility has a consultant pharmacist it trusts. Nothing about that relationship needs to change. The program supplies the standard, the training, the follow-through structure, and the system, and the existing pharmacist works inside it.

Right when: the relationship is good and the structure is the gap. This is more common than it sounds. Many facilities have a capable consultant who has been doing careful work on paper for years, and what is missing is not judgment but continuity between visits.

What actually changes. The pharmacist runs the same visit, to a defined standard, and records it in a system rather than in a report. Findings persist between visits instead of being restated. The facility can see the record without asking for it.

What does not change. Who they work with, what they pay them, and the professional judgment they rely on.

Honest about the hard part. This only works if the pharmacist is willing. A standard imposed on a consultant who did not agree to it produces compliance theatre, and the facility ends up with worse information than before, because the pharmacist starts working to the form rather than to the facility.

So ask them first, and ask properly. Show them the standard, not a demand. Most experienced consultants recognize their own practice in it, and the ones who push back usually have a reason worth hearing. A consultant who objects to recording findings with owners and dates is telling you something useful about how they work.

Watch for the halfway state. The most common failure of Model A is a pharmacist who adopts the system for the visit record and keeps the follow-up in their own notes. That produces a system that looks maintained and a program that is not. If findings are closing without evidence attached, the model is not being run.

Model B · Program-matched pharmacist

The facility is matched with a consultant pharmacist working under this standard, trained on it, and accountable to it.

Right when: there is no incumbent, the incumbent is retiring, the relationship has run its course, or the facility is opening and has nobody yet.

What matching should actually consider. Not only geography, though geography determines whether a weekly cadence is sustainable at all. Also: setting experience, since an ASC is not a hospital and not a retail pharmacy; the facility’s case mix and whether the pharmacist has seen it; state licensure and currency; and availability that genuinely matches the cadence being sold rather than a calendar that is

already full.

Set first-period expectations honestly, in advance. Expect the first visit to surface more than a steady-state visit will, because a new set of eyes always does and because an incoming pharmacist inherits whatever the previous arrangement did not catch. Say that to the administrator before the first visit rather than explaining it afterward, or a normal first visit reads as a crisis.

A match is a relationship and it takes a period to settle. The first visit is largely orientation. The second is the first real one. Judge fit at the third, not the first.

Transition, where there is an incumbent. Ask for the last several visit reports, the open findings, and the policy manual before the first visit. If they are not available, that absence is itself the baseline. Do not characterize the previous consultant's work in writing. Document what you find now and let the record speak, because a report that reads as criticism of a predecessor tells the facility how you will speak about them later.

Say what happens if the fit is wrong. A facility should be able to ask for a different pharmacist without ending the engagement, and should be told that at the start. A facility that feels stuck with a poor fit stops sharing information long before it complains, and by then the program has been degraded for months.

Model C · Facility-led with pharmacist oversight

The Facility Pharmacy Lead runs the daily routine and a defined portion of the periodic review, with a pharmacist providing oversight, review, and access without being physically present at every interval.

Right when: the facility is remote, the interval between required on-site visits is long, or the facility wants more frequent touch than an on-site cadence economically supports.

Confirm your state before considering this model. State boards differ substantially on what a consultant pharmacist must do in person and how often. Several require on-site inspection at a defined frequency, several require a written report from that inspection, and some are silent. Where a state requires on-site presence, remote oversight supplements the required visit and never replaces it. Where a state is silent, the absence of a rule is not permission, and it is worth a written question to the board rather than an assumption.

Honest about: a pharmacist who is never in the building will miss things that only exist in the building. A drawer that does not close. A sharps container in the wrong place. A nurse who hesitates before answering. Part 5 loses real resolution at a distance, and any honest version of this model says so rather than selling remote as equivalent.

5.7 Running a portfolio

Most of this document describes a visit. This section describes the pharmacist's own week, because a consultant covering ten facilities faces problems a consultant covering one never encounters, and those problems are where quality quietly degrades.

5.7.1 What changes when there is more than one

Comparison becomes possible, and it is the most valuable thing available. A finding at one facility is a finding. The same finding at six is a signal about how a group trains, buys, or staffs. Nothing visible inside a single visit tells you that.

Consistency stops being automatic. One pharmacist is consistent with themselves without trying. Two pharmacists across twelve facilities will diverge unless something holds them together, and that something is the standard, not goodwill.

Memory stops working. At three facilities a pharmacist remembers what is open where. At ten they do not, and the failure is silent, because nothing announces a finding that was forgotten.

Travel becomes a material cost. At a weekly cadence, route quality determines how many facilities a pharmacist can serve well, which determines the economics of the whole practice.

5.7.2 The pharmacist's week

Before each visit, ten minutes. Open findings sorted by age, what changed since last time, anything due before today, and any expiration inside ninety days. Ten minutes of preparation changes the visit from a survey into a follow-up.

Group facilities geographically, not alphabetically. Route so a day is two or three facilities in one area rather than three across a metro. The time saved is time available for the visit rather than for the car.

Protect the documentation window. The 24-hour submission target in section 1.7 fails first when a pharmacist books visits back to back with no gap. Build write-up time into the day as if it were a visit, because it is part of the visit. The goal is to write it while you still remember the room.

Keep one slot open per week. Something will happen: a discrepancy, a survey, a facility that needs an unplanned visit. A fully booked week means the unplanned thing displaces a scheduled visit, and a displaced visit breaks the cadence commitment.

Batch the portfolio review. Once per period, look across all facilities rather than at any one: what is overdue anywhere, which findings appear at more than one site, which facilities are trending the wrong way, and where you have not been in longer than the cadence claims.

5.7.3 Keeping quality consistent as volume grows

The failure mode is drift, and drift is invisible from the inside. A pharmacist does not notice their visits getting shorter. Every individual decision is reasonable, and the aggregate is a different standard than the one they started with.

Three controls, in order of usefulness:

Read your own old records. Pull a visit record from a year ago and compare it to last week's. Most drift is visible immediately and only in comparison. This costs an hour and it is the single most effective control in this section.

Have someone else read them. A second pharmacist reading two of your records per year will see things you cannot. Inside TOM this is scheduled. Independently, find a peer and trade.

Watch the leading indicators of drift, in yourself and in anyone you supervise:

- Visits getting shorter with no change in the facilities
- Fewer findings per visit over time, without a corresponding drop in recurrence
- Narrative summaries becoming similar across different facilities
- Verification queues clearing faster than they used to
- Findings closing without evidence attached
- Records consistently submitted at the 24-hour edge rather than the same day

Any one of those is a question, not a verdict. Several together, sustained, is drift.

5.7.4 When more than one pharmacist covers a portfolio

Same standard, or the portfolio is not a portfolio. Two pharmacists working to different standards produce records that cannot be compared, which destroys the one advantage multi-facility oversight has.

Cross-read. Each pharmacist reads a sample of another's records periodically. Not as audit. As calibration, since the disagreements are the useful part, particularly on severity.

Handover has to be a document, not a conversation. When a facility changes pharmacists, the incoming one should be able to start from the record alone: open findings, recurrences, accepted risks, the relationships, and what has been tried and failed. If a handover requires a phone call, the record was insufficient, and that is worth fixing before it is needed. Form C-32 is the handover record.

One person owns each facility. Shared ownership produces facilities where each pharmacist assumes the other raised it.

5.7.5 What a group buys that a single facility does not

For a management company or a multi-site owner, the periodic question is not how each facility is doing. It is:

- Which findings appear at more than one site, since those can be fixed once, at the group level, rather than ten times
- Which facilities are trending differently from the rest, and why
- Whether the standard is being applied consistently, which is a question about the pharmacists rather than the facilities
- Where a policy written centrally does not fit a specific site, since a group-wide policy that does not fit

produces workarounds at the sites where it does not

The most valuable finding in a portfolio is a pattern, and a pattern is invisible to the person who only ever sees one facility.

5.7.6 Scheduling and routing

A portfolio is a scheduling problem long before it is a quality problem, and the pharmacist who schedules badly discovers it as quality problems.

Cadence is set by risk, not by fairness. Facilities do not deserve equal time. Volume of controlled substances, findings history, staff turnover, survey window, and how recently the program stood up all move a facility up or down. Write the cadence per facility, review it quarterly, and change it deliberately rather than by drift.

Build the calendar backward from the fixed points. The survey window, the biennial due date, license renewals, and any facility's committee meeting the summary has to reach are immovable; visits are placed around them so the work lands where it is useful rather than where the calendar was empty.

Cluster geographically, but never at the cost of the cadence. Two facilities in the same corridor on the same day is efficient; a facility pushed three weeks late so it could share a drive is a facility whose cadence was decided by fuel. When the two conflict, cadence wins.

Leave the collapse room. Section 1.7's close conditions fail first when visits are booked back to back. Every visit day needs slack for the discrepancy that turns a routine visit into an investigation, and the honest planning number is fewer facilities per day than the drive time suggests.

Know your own capacity number. Track actual door-to-door time including travel, write-up, and follow-through, not just the on-site hours, and hold a real number for how many facilities one pharmacist carries at each cadence. Portfolio growth beyond that number is a hiring decision, not a scheduling one, and 5.7.3's quality-consistency problem is what arrives when the number is exceeded quietly.

Unscheduled visits have a trigger list, agreed in advance. A suspected diversion, a serious discrepancy, a survey notice, or a change of Lead pulls a visit forward; nothing else does. Without the list, urgency is decided by whoever called most recently.

Routing details that matter more than they should: confirm access and badge arrangements before driving, know the days a facility does not operate, avoid arriving during the opening rush, and keep the last hour of the day free for the write-up while the visit is fresh, because a report written the next morning is a report written from memory.

In TOM MMS the portfolio view shows each facility's last visit and the time since, so the scheduling decision starts from where the gaps are; route planning across a portfolio is in development at this writing, and this section is the method it is being built to serve.

5.7.7 Scaling past yourself

A solo consultant reaches a ceiling that has nothing to do with skill. Section 5.7.2 sets the capacity

number: door-to-door time including travel, write-up, and follow-through, not on-site hours. When the portfolio exceeds that number, there are only three honest options. Take fewer facilities. Reduce the cadence, which reduces the service. Or add a person. This section is about the third, because it is the one nobody prepares for and the one that most often damages a practice that was working.

Standardize before you hire, not after. The single most common failure is hiring first and discovering that everything the practice knows lives in one head. Before a second pharmacist is useful, four things have to exist outside you: the visit runs to the written standard rather than to your habits, the findings carry the five elements without you editing them, the facility record is complete enough that somebody else could take the next visit cold, and the close conditions are applied the same way every time. If those four are true, a second pharmacist is an addition. If they are not, a second pharmacist is a second standard, and the portfolio quietly becomes two practices sharing an invoice.

Employee or contractor is a real decision, not a formality. The tests are factual and they turn on control rather than on what the agreement is titled. It is worth stating plainly what each choice actually means for a practice built on a standard.

	Employed pharmacist	Contracted (1099) pharmacist
Control over how the work is done	You can direct method, schedule, and sequence, which is exactly what a standard requires	Direction over method is the thing that most undermines contractor status, so the standard has to be an agreed deliverable rather than an instruction
What you are buying	Capacity you can shape	A result to a specification
How the standard travels	Through training and supervision	Through the engagement document, which must incorporate the standard by reference
Cost shape	Fixed, plus employment burden	Variable, higher per visit, no burden
Coverage risk	Yours to manage, including leave	Theirs, which means a facility can be left uncovered unless the agreement says otherwise
Quality assurance	Supervision plus 10.5 record review	10.5 record review, contractually required, or you have no route to it

Classification is decided by facts and by the applicable federal and state tests, not by preference, and it is a question for counsel and an accountant rather than for this document. What this document does say is that whichever you choose, **the standard must be an obligation somewhere**: in the employment expectation, or in the engagement document. A contractor who has not agreed to work to the standard will work to their own, and their own is not visible to you until a facility notices the difference.

What has to be in place before the first visit they run alone.

1. **The standard, in their hands, read.** Not summarised. Parts 1 through 5, and the variant part for any setting in their assignment.

2. **Supervised visits, both directions.** They observe you, then you observe them, at the same facility if possible so the comparison is real. Two of each is a reasonable floor and it is worth more than any interview.
3. **A calibration on severity.** Give them the same set of findings you would score and compare. Severity drift is the most common divergence between two competent pharmacists and it is invisible until someone compares.
4. **Named facility ownership.** One person owns each facility, per 5.7.4. Shared ownership produces facilities where each pharmacist assumes the other raised it.
5. **Access, credentials, and the paperwork.** Their own credentials in the system rather than yours shared, their own licensure verified and on file, their own professional liability coverage confirmed, and the facility informed of who is coming.
6. **A first-quarter review date, agreed in advance.** Not as a probation. As the calibration checkpoint, which is easier to hold if it was scheduled before there was a reason for it.

What to hand over first, and what to hold. Hand over the facilities that are running well, not the difficult ones. This is counterintuitive and it is the right order. A new pharmacist at a healthy facility learns the standard as it is meant to run and builds a relationship on ordinary visits. A new pharmacist at your worst facility inherits a problem they did not create, without the relationship capital to fix it, and both of you conclude the hire was a mistake. Hold the difficult ones until the standard is demonstrably shared.

What the founder’s role becomes, and it changes. Once someone else runs visits, your work is no longer the visits. It is calibration, escalation, relationships at the account level rather than the facility level, and the quality assurance in 10.5. Practices fail at this transition by trying to keep doing both, which produces a person doing two jobs badly and a second pharmacist who is never trusted with anything hard.

Where scaling actually breaks. Not at capacity, which is arithmetic and visible. It breaks at consistency, which is invisible until a facility mentions that the last pharmacist did it differently. That is why 10.5’s peer record review is not optional above one pharmacist and why the cross-read in 5.7.4 exists. Quarterly, two records each, reviewer named, drift treated as a finding with an owner and a date, exactly like a facility finding.

In TOM MMS a second pharmacist works in the same records rather than in their own copy, findings carry the same required elements whoever writes them, and the portfolio view shows both pharmacists’ facilities together, which is what makes the cross-read in 5.7.4 a query rather than an exchange of documents. None of that produces consistency by itself. It makes inconsistency visible, which is the part that is hard to do on paper.

5.8 When the engagement gets hard

Most visits are quiet. The ones that are not are where a consultant’s judgment actually gets tested, and where the difference between a professional and a contractor shows. Section 1.2 governs all of these: the posture does not lapse because the situation is uncomfortable.

The facility disputes a finding. First, take it seriously rather than defending it. You are working from a fraction of the building’s hours and they are not, so a disputed finding is often a finding built on a gap in what you were able to see. Ask what you missed. If the answer resolves it, correct the finding and say plainly that you corrected it, which costs nothing and buys more credibility than being right would have. If it does not resolve it, the finding stands as written, the facility’s disagreement is recorded alongside it rather than instead of it, and the decision about what to do belongs to the facility. You do not need agreement to record a fact, and you do not get to require agreement either.

You are asked to soften, delay, or remove a finding. By an administrator, an owner, a medical director, or a colleague. The answer is the same regardless of who asks and how reasonable the reason sounds: the record says what was found. What the facility does about it is theirs, including accepting the risk, and accepted risk has a home in section 4.4 precisely so that a legitimate business decision has somewhere to live that is not a deleted finding. Offer that path, because a no with a route forward is accepted and a bare no is resented. If the pressure continues, it is no longer a finding question, it is an independence question, and section 10.1 governs.

Records for a period are missing. Not thin, absent. A month of temperature logs, a stretch of the CS log, an entire cart check history. Do not reconstruct them and do not accept a reconstruction offered to you, because a reconstructed record is a false record with a helpful motive. Document the gap: what is missing, for which dates, discovered how, and what the facility says about it. Then work forward from today. A documented gap with a start date is a finding a facility can close. An invented record is a finding nobody can ever close.

You find something that looks like diversion, mid-visit. Stop the sampling and secure the position rather than investigating. Do not interview anyone, do not confront anyone, and do not begin building a case. Preserve what you found exactly as you found it, document the facts without adjectives or inference, and escalate the same day to the person named in the escalation path, usually the administrator and the medical director. From that point the facility owns the investigation, and it will involve people whose job this is and possibly counsel and law enforcement. Section 10.3 is why you do not touch it: the person who audits custody keeps the cleanest custody in the building, and that includes not handling evidence.

A finding points at a named individual. It stops being your document. Record the pattern, hand it to facility leadership, remain available, and do not recommend discipline. Section 1.2 still governs the framing: the first question is what the system asked of that person that they could not reliably deliver. Very often the honest answer changes what the facility does with it.

You discover your own error after the fact. A finding you got wrong, a close you signed that the record did not support, a severity you called too low. Report it yourself, in writing, before anyone finds it. Correct the record by amendment rather than by replacement, so the original and the correction both survive. This is the single clearest test of whether the amendment culture you teach is something you actually believe, and a facility that watches you do it will believe the rest of the standard.

The facility will not act, visit after visit. Findings age, closure dates pass, nothing moves. Escalate deliberately rather than repeating yourself: raise it once in writing to the administrator with the specific consequence named, then to the governing body or medical director through the agreed path. If the pattern persists, the honest question is whether the engagement is producing a program or producing documentation of a program, and section 5.9 covers the answer, including ending it.

You believe a patient is in danger right now. Everything else in this section can wait for a written finding and the next meeting. This cannot, and the ordinary escalation path is too slow for it. Say so immediately, out loud, to whoever is present and in charge, and say it plainly rather than diplomatically: what you saw, why you think it is dangerous, and what you think should stop. Being wrong in that moment costs you some embarrassment. Being right and quiet costs something else entirely.

Then write it down the same day: what you observed, what you said, to whom, at what time, and what was decided. Not to protect yourself, though it does, but because an urgent verbal warning that nobody recorded is indistinguishable afterward from a warning nobody gave.

The limits still apply and they matter more here, not less. You are not taking over the patient's care, you are not overruling a clinician, and you are not the person who decides what happens next. Section 5.9 does not suspend because the situation is urgent. What you own is that the person who can decide knows what you know, immediately and unambiguously.

Something outside your scope frightens you. Sterile technique that is not your remit, a staffing level you think is unsafe, a clinical practice that worries you. You are not the facility's operator and 5.9 says so. You are also a licensed professional who saw it. Raise it once, in writing, to the right person, factually and without a recommendation you are not qualified to make. Then let it go, and record that you raised it. Both halves matter.

The relationship itself has failed. It happens, and staying in a relationship that has stopped working produces the worst artifact in this document: a signed visit record for a program nobody is running. Section 10.4's records-are-never- hostage rule applies at the exit, the handover in Form C-32 exists so the next pharmacist starts from the truth, and leaving well is a professional act rather than a failure.

The thread through all of them. Secure, document factually, escalate to the person whose decision it is, and stay in your lane while remaining available. None of these is resolved by being the smartest person in the room, and most of them are made worse by trying.

5.9 The limits of this part, stated plainly

A consultant pharmacist does not own the facility’s compliance. The facility does. This is not a liability dodge, it is the operating reality: a consultant who behaves as though they own it creates a facility that has outsourced thinking about it, and that facility is more dangerous, not less.

No program guarantees a survey outcome. Nobody can promise a clean survey and anyone who does is selling something. What a program does is ensure that when a surveyor asks, the answer exists, is documented, and can be found.

The pharmacist is not the auditor of record. Findings here are professional observations against rules and standards. They are not a legal determination, and where a question is genuinely legal the answer is counsel, not a consultant.

Judgment is fallible and should be reviewable. Every determination in this program is documented in a way that someone else can examine later, including someone who disagrees. A program whose conclusions cannot be second-guessed is a program whose conclusions cannot be trusted.

PART SIX

The Operating Cycle

PART 6 · THE OPERATING CYCLE

What this part is for. A program that repeats is not the same as a program that improves. This part is the cycle that turns a series of visits into a trajectory: what happens at onboarding, what each position in the cycle contributes, what the facility receives periodically, and how the medication program feeds the facility’s own quality program.

Inside: why a cycle rather than a schedule, onboarding, the cycle positions, what the facility receives, the quality study, the QAPI connection, what a year of the cycle produces, and what happens when the facility is surveyed or inspected.

6.1 Why a cycle rather than a schedule

The four layers describe a program. The cycle describes how it improves.

A visit is an event. A cycle is what makes a series of events compound: each visit informed by the last, education aimed at what the record actually showed, and a periodic step back to ask whether the facility is stronger than it was.

Cadence varies. State boards differ, facilities differ, and a busy multi-OR center with high controlled substance volume needs a different rhythm than a smaller center doing pain procedures. The cycle below is written in terms of positions rather than calendar dates: an onboarding pass, an early emphasis, a middle emphasis, a late emphasis, and an annual step back. Map them onto whatever interval your state and your facility require.

What TOM Pharmacy Consulting, LLC does, and why

Weekly for surgery centers and freestanding emergency facilities. Monthly for long-term care and any facility on a monthly cycle.

Weekly is more frequent than the market norm, and it is a deliberate choice rather than a service-level flourish. Three reasons.

The verification window. Controlled substance entries carry a review window measured in days, not weeks. On a monthly cadence, most of a month’s entries are reviewed well after the window has closed, which means the review is retrospective by design. Weekly means the records are reviewed while the week they cover is still current, and while the people who created them are still here and still remember.

Investigability. A variance found seven days after it arose has a defined population of people, cases, and shifts to examine. The same variance found thirty days later frequently has none, because per-diem staff have rotated, the case list is long, and memory has gone. The gap between finding a discrepancy and being able to explain it is the whole difference between a resolved discrepancy and a reported loss.

Compounding. The cycle in this part depends on findings closing between visits and education landing near the finding that prompted it. On a weekly cadence a corrective action gets checked four times in the interval a monthly program checks it once. Follow-through stops being an act of memory.

Where weekly is not the answer. Long-term care runs monthly at minimum because the regimen review requirement drives it and the work is resident-by-resident rather than system-by-system. Low-volume facilities holding few or no controlled substances may not warrant it. Some states specify a minimum frequency, and where they do, that is a floor to exceed rather than a target to meet.

Cadence is a commitment, not a preference. Whatever interval a facility adopts goes in writing, and it is the interval they will be held to. A facility whose policy says weekly and whose records show every eleven days has created its own finding, and it is the easiest one a surveyor will ever write.

Scheduling the visit

Hold the cadence rather than intending it.

Every visit ends with the next one scheduled, before the pharmacist leaves the building. A visit not scheduled is a visit that slips, and cadence is the one element of this program that cannot be recovered retroactively. You can close a finding late. You cannot conduct last month’s visit.

Track the series, not the appointment. What matters is not when the next visit is, it is whether the interval between visits has been maintained across the period. Those are different questions, and only the second one appears in a survey. A program that records the next date on each visit still cannot answer “were you here every week last quarter” without someone counting.

Detect the miss. A skipped visit should surface as a gap rather than as an absence, because an absence is invisible. Nothing announces a visit that did not happen.

6.2 Before the cycle starts: onboarding

The single highest-value work in the program, and the part most often skipped because it is unbillable enthusiasm at the start of a relationship.

This section assumes a center that is already operating. For a center that has not opened yet, see Part 8.

Onboarding establishes what everything afterward is measured against.

Policy and procedure review. The full manual, read against the facility's accreditation body and state board, with rewrites where it is stale. Most facilities have a manual that was correct when it was purchased. Very few have one that describes what the facility actually does, and the gap between the two is where surveys are lost.

Baseline assessment. A full pass across medication management, controlled substances, storage, emergency equipment, and documentation. Not a visit. A census. The point is to know where the program starts, because without a baseline every later claim of improvement is an assertion.

Formulary and workflow review. What they stock, what they use, what they throw away. Where medications physically live and who touches them.

Licensure and registration confirmation. State licenses, DEA registration, CSOS enrollment where applicable, and expiration dates recorded so nothing lapses quietly.

Pharmacy Lead named and prepared. The single most durable thing accomplished during onboarding.

Onboarding output is a prioritized gap list, not a report card. The list is the agenda for the cycle.

6.3 The cycle positions

Four positions, mapped onto whatever interval the facility and the state require. Each has a purpose, a focus, deliverables, and a test of whether it actually happened.

A note on why this works. AAAHC describes accreditation as a continuous journey across the full accreditation term rather than an event that happens when a surveyor arrives. The cycle below is the pharmacy program’s version of that idea. A facility that prepares in the eight weeks before a survey is preparing. A facility running a cycle is ready.

PART 6 · THE OPERATING CYCLE

The Cycle Positions

Position 1 · Baseline and structure

Purpose. Establish the routine and prove that the follow-through discipline is real.

Focus. Work the highest-priority items from the onboarding gap list. Confirm the visit cadence and then hold it, because a cadence that slips in the first period will slip permanently.

Set the follow-through discipline now. The first due date that passes without a conversation teaches the facility what due dates mean in this program, and that lesson is very hard to un-teach. If a date is going to be missed, the escalation happens before it is missed, not after.

Name the Pharmacy Lead if onboarding did not, and begin their curriculum.

Deliverables

- Prioritized gap list, every item with an owner and an agreed date
- First leadership summary, stating plainly where the facility stands
- Confirmed visit cadence, in writing
- Pharmacy Lead named, with training started

The test. At the end of this position, can the administrator state, without looking it up, what the top three pharmacy priorities are? If not, the summary was written and not read, and the next one needs to be shorter.

Position 2 · Targeted education

Purpose. Convert findings into capability, so the same findings stop appearing.

Focus. Education aimed at what the record actually showed, not a generic curriculum. If witness documentation was the gap, teach witnessing. If beyond-use dating was the gap, teach beyond-use dating and then walk the storage areas with the staff who were just taught.

This is the position that separates a program from a visit schedule. Generic annual training satisfies a requirement. Education aimed at this facility's own findings changes behaviour, and the difference shows up in the next period's findings rather than in an attendance sheet.

Corrective actions from Position 1 should be closing now. Anything not closing gets diagnosed rather than re-dated: is the owner wrong, is the date unrealistic, or is the fix impractical? A finding re-dated twice has a cause that nobody has named.

The first trend becomes visible here, and it is the first time you can say something about direction rather than status.

Deliverables

- Education sessions documented, with attendance per person
- Corrective actions closed with evidence accepted

- First trend, even if it is only two data points
- Any recurrence identified and converted to a CAPA

The test. Did the findings that drove the education stop recurring? That is the only measure of whether education worked. Attendance is not.

Position 3 · Readiness and rehearsal

Purpose. Pressure-test rather than inspect, while there is still time to fix what breaks.

Focus. Everything in this position is deliberately adversarial, and the facility should be told that in advance so nobody feels ambushed.

Mock survey. Run against the standards of the body that actually accredits this facility. Ask staff the questions surveyors ask and note who cannot answer. Someone being unable to answer is not a failure, it is the finding, and it is far better discovered now.

Controlled substance audit readiness. Run the way an investigator would run it, not the way a friendly reviewer would. Pick a date range, pick a drug, and follow every unit from receipt to disposition. Gaps that a routine reconciliation smooths over are visible in a trace.

Drills. Malignant hyperthermia at minimum, since it is the highest-consequence and lowest-frequency event in the building. Diversion response. Emergency medication access, timed.

Worth knowing before you propose one: under 42 CFR 416.54 the facility already owes exercises testing its emergency plan at least annually, plus emergency preparedness training documented at least every two years. A properly run and documented MH drill can serve both the pharmacy program and an obligation the facility carries anyway, which is usually the argument that gets it scheduled.

Quality study begins. See 6.5.

Use the published deficiency data. AAAHC publishes an annual Quality Roadmap analyzing the most common deficiencies found across surveys in the prior year, and makes it freely available. Reading it and checking the facility against the most common findings is the cheapest readiness work available, because it tells you what surveyors are actually citing rather than what you assume they cite.

Deliverables

- Mock survey findings, treated as real findings with owners and dates
- Controlled substance trace, documented
- Drill records, including what went wrong, because a drill where nothing went wrong was not a drill
- Quality study underway with a defined measure

The test. Did the rehearsal find something? A mock survey that produces no findings was not adversarial enough, and the real one will not be so kind.

Position 4 · Durability and evidence

Purpose. Prove the program can carry itself forward, and assemble the evidence so that survey preparation becomes retrieval rather than a scramble.

Focus. Step back rather than inspect.

Annual program review. What changed across the full period, what improved, what did not, and what the program should do differently next year.

Trend report. Findings by severity over time, closure rates, recurrences, accepted risks. Direction rather than a snapshot.

Competency assessment. Every staff member, current or not, with gaps named.

Evidence pack. Assembled so a surveyor’s request is answered by retrieval. Policies, competency records, findings and closures, drill records, quality study, controlled substance records, temperature and equipment logs.

Policy review. The annual pass, dated, against the current standards of the accrediting body. Standards versions change, and a manual written against a retired version is a finding waiting to be made.

Deliverables

- Year-over-year trend report
- Survey-readiness evidence pack
- Competency assessment across staff
- Updated policy manual with a dated review record

The test, and it is the real one. If the pharmacist changed tomorrow, could a new one pick this program up from the record alone and continue without interviewing anyone? A program that fails that test is a relationship, not a program.

6.4 What the facility receives periodically

A leadership summary, on the facility's governing cadence, that a board can read without translation. It answers five questions and no more.

1. **What was reviewed.** Visits conducted, areas examined, staff trained.
2. **What was found.** Findings by severity, with the critical ones named.
3. **What was fixed.** Closures with evidence accepted.
4. **What remains open.** Including anything overdue, and anything recorded as accepted risk with the name attached.
5. **Where the program is going.** Trend against the prior period, and the one or two things that matter most next.

Written for a board, not for a pharmacist. No abbreviations without expansion, no regulatory citation without a plain-language sentence next to it, and no number without its denominator. "Three open findings" means nothing. "Three open, down from eleven, with two overdue" is a status.

Assembled from the record, not written from memory. If the summary requires the pharmacist to remember the period, the record was not kept properly and the summary is a reconstruction.

Length discipline. One page, two at most. A summary long enough to require skimming will be skimmed, and the thing that gets skipped is always the open items. If there is more to say, say it in the meeting.

Feed the governing body deliberately. CMS requires an ASC to have a quality assessment and performance improvement program, and accreditors expect the governing body to receive and act on quality information. Pharmacy is part of that program whether or not anyone has been reporting it as such. A summary written so it can go straight into the quality committee packet, unedited, is worth more to an administrator than one that has to be rewritten first.

6.5 The quality study

Once per period, one question studied properly.

Structure it to match what the facility's accreditor expects. AAAHC consolidated its quality improvement study template from ten steps to six under its v43 standards, and v44 is current as of this writing, effective December 16, 2025, with v45 through public comment in spring 2026 and adoption ahead. Confirm the current version, template, and step count before designing a study, and follow the facility's own framework rather than a generic one, because a well-run study in the wrong format still produces a finding.

Choose a topic the record suggests, not one that is convenient. Good sources of topics, in order of usefulness:

1. Your own recurring findings. A finding that has recurred twice is a study asking to be written.
2. The published deficiency data. AAAHC's annual Quality Roadmap reports the most common deficiencies from the prior year's surveys and is freely available, now in two editions; the comprehensive edition is the ASC-relevant read. A topic that is commonly cited nationally and unexamined here is a strong candidate.
3. A near miss. The best studies usually start with something that almost went wrong.

Topics that work in a pharmacy program: controlled substance discrepancy rate and cause; temperature excursion frequency, cause, and time to corrective action; waste documentation completeness; medication labeling in the procedure area, measured by observation rather than by record; expired stock recurrence by location; time from finding to closure.

Design rules

- Define the measure before collecting, and write down what number would mean the intervention worked
- Collect over a real interval, not a convenient afternoon
- Measure the same way at the end as at the beginning
- Report what actually happened, including if nothing improved

The requirement to report results is federal, not editorial. Under 42 CFR 416.43(d)(2) the ASC must document its performance improvement projects, and the documentation must at minimum include the reason for the project and a description of the project's results. It does not say favourable results.

A study with a predetermined conclusion is not a study. If you already know the answer, measure something else. The value is in occasionally being wrong about your own facility, and a study designed to confirm what the pharmacist already believes wastes the one opportunity per period to find out otherwise.

A study that shows no improvement is a valid study, provided it says so and says what will be tried next. A file of studies that all succeeded is not a quality program, it is a marketing file, and an experienced surveyor reads it that way.

6.6 The QAPI connection

Every Medicare-certified ASC is required to run a quality assessment and performance improvement program. The Conditions for Coverage at 42 CFR 416.43 make it data-driven and ongoing: the facility measures quality indicators, tracks adverse patient events, shows measurable improvement, and the governing body owns the results. Surveyors read the QAPI binder the way this standard reads a controlled substance log: for whether the machine runs, or merely exists.

The pharmacist does not run the facility's QAPI program. The pharmacist supplies its medication component, and the operating cycle already produces every input that component needs. What most facilities lack is not data but the connection.

The medication indicator set, drawn from records the cycle already keeps and reported as trends with denominators:

- Controlled substance variance rate, and time to closure
- Temperature excursions, and the share with completed corrective action
- Expired or beyond-use stock found per visit
- Witnessed-waste completeness
- Findings open past their due date, by severity
- Medication errors and adverse drug events reported, with the reminder that a rising count in a young program usually measures reporting culture improving, not practice worsening

The feed. Quarterly, the indicator table goes to the QAPI committee alongside the leadership summary, and the pharmacist attends or sends two sentences per indicator: the trend, and what is being done about it. Section 8b's "what is coming" is the same content pointed forward; QAPI is where it lands on an agenda.

One improvement project a year. The quality study in 6.5 is built to be that project: pick the weakest indicator, fix the system behind it, and show the before and after. A completed medication improvement project, documented from baseline to result, is the strongest single artifact a facility can hand a surveyor.

The governance line. The governing body reviews, and the medical director signs, the medication component's periodic summary, because the rule makes the program theirs. The pharmacist who writes the two-minute version for that audience is doing Module 8's work in its natural venue.

What QAPI is not. Not a blame instrument, and never a reason to name individuals in an indicator. Patterns go up; people conversations stay in Module 5's lane. An indicator set staff fear becomes an indicator set staff quietly starve.

> **PROGRAM** **Medication Quality** · Owner: the pharmacist supplies the medication component; the governing body owns the program · Cycle: indicators assembled and reported quarterly, one improvement project per year · Artifacts: the indicator table, the improvement project record, and the governing body report · Measure: the six indicators themselves, each with its denominator and its trend

Form C-33 is this indicator table on paper, and Form C-34 is the improvement project record.

In TOM MMS the indicator table assembles from the same records the visits already verify, and the compliance score and reports give the QAPI packet its data pages. The two sentences per indicator are the pharmacist’s part.

6.7 What the cycle produces over a year

- A policy manual that describes what the facility actually does
- A named, prepared Pharmacy Lead and a staff with documented competency
- A findings history with closure evidence attached
- A trend that shows direction rather than a snapshot
- Rehearsal documentation for the high-stakes scenarios
- One quality study with a real conclusion
- An evidence pack that makes survey preparation retrieval

None of that exists after a year of visits without a cycle. All of it exists after a year of visits with one, and the difference in effort per visit is smaller than it sounds.

Running this without software

The leadership summary is where the cost shows up, because it is assembled rather than written.

Done properly it reports what was reviewed, what was found by severity, what closed with evidence accepted, what remains open and overdue, and the trend against the prior period. Every one of those numbers already exists inside the visit records. Producing the summary by hand means opening each of them and counting.

That is an afternoon, per facility, per period. It is also the first thing to get shortened when time is short, and a shortened summary is where “three open findings” appears without its denominator and stops meaning anything.

In TOM MMS the summary is generated from the same records the visits already produced, which is the difference between reporting and re-typing. It also means the numbers in the report and the numbers in the system cannot disagree, which they otherwise eventually will.

6.8 When the facility is surveyed or inspected

Everything in this document is preparation for days the facility does not choose. Three kinds of visitor arrive, they arrive for different reasons under different authority, and a pharmacist who cannot tell them apart is not useful on the day.

Who arrives	Under what authority	What they mostly want
An accreditation surveyor	The facility's voluntary accreditation, often carrying deemed status for Medicare	Evidence that the facility's own program works: records, staff who can answer, and improvement that is documented
A state licensure surveyor	The facility's licence to operate, and the state's own rules	Compliance with the state chapter, and often the same medication records read against different citations
A DEA diversion investigator	Federal registration for controlled substances	Records, security, and a physical inventory. A narrower question, asked more precisely

Any of the three may also arrive because somebody complained, or because a reported event triggered it. A complaint-driven visit is usually narrower and sharper than a routine one, and it is the one most likely to reach the medication layer, because complaints about medications are common.

Before: the only part the pharmacist controls

The work is already in this document, and the honest summary is that survey readiness is not a project. It is the ordinary operation of the nine programs, plus one thing: records that retrieve. Form C-36 exists so that when somebody asks for the last reconciliation, the answer is a folder rather than a search. Time the retrieval occasionally, as Topic 10 says, because the difference between a program that looks credible and one that does not is often measured in minutes at a filing cabinet.

The mock survey is the highest-value visit you will ever run. Once a year, walk the facility as a surveyor would, ask the questions in Handout D-19 of the people who would actually be asked, and write the findings as findings. A mock survey that produces nothing was not a mock survey.

During: what the pharmacist actually does

Most of the time the pharmacist is not in the building when a surveyor arrives, which makes the preparation above the whole of the contribution. Where the pharmacist is present or is called:

1. **Be findable and be useful.** The facility should know how to reach you the same day, and that expectation belongs in the engagement agreement rather than in goodwill.
2. **Answer what is asked, from the record.** Not more. A pharmacist filling silence with context is how a narrow question becomes a broad one. If the answer is in a record, produce the record. If it is not, say that it is not.

3. **Never speculate about cause, and never speculate about a person.** Section 1.2 governs here with particular force, because a surveyor is not the audience for a theory.
4. **Do not correct a record during a survey.** An amendment made while an inspector is in the building will be read as exactly what it looks like, whatever its intent. Note what needs correcting and do it afterward, on the record, per the amendment rule.
5. **Write down what was asked.** Questions asked are the best prediction of next year's questions, and almost nobody records them.

After: the plan of correction

A survey that finds something produces a written statement of deficiencies, and the facility answers it with a plan of correction on a deadline. The medication findings land on the pharmacist, and this is the single moment in the cycle where the facility most needs one.

A plan of correction is not a promise to try harder. Every accrediting and licensing body wants substantially the same five things, and a plan missing any of them tends to come back:

1. **What will be done** about the specific instance found.
2. **What changes so it cannot recur**, which is section 4.5's corrective action rather than an action item. This is the element weak plans skip, and it is the reason repeat deficiencies exist.
3. **Who is responsible**, by role and by name.
4. **By when**, with a date rather than a phrase.
5. **How the facility will know it worked**, and for how long it will keep checking. A measure and a monitoring period, which is the same discipline as the quality study in 6.5.

Two failures to help the facility avoid. The first is a plan written to close the citation rather than to fix the condition, which produces the same citation at the next survey and a harder conversation about it. The second is a plan that commits the facility to something it will not sustain, such as a daily double-check nobody has staffing for, which converts one deficiency into a future finding of not following your own policy.

Where the pharmacist stops. The facility submits the plan and owns it. The pharmacist supplies the medication content, the corrective action design, and the measure, and does not sign it.

If a DEA investigator arrives

This is the visit facility staff are least prepared for, and the one where preparation has to happen in advance because there is no time on the day.

What the pharmacist should make sure the facility knows, before it happens. An administrative inspection normally begins with a Notice of Inspection, DEA Form 82, whose required contents are set by federal regulation and which states the registrant's rights on its face, including that consent is voluntary, that it may be withdrawn, and that anything incriminating found may be used in a criminal proceeding. Consent may be declined, in which case the agency may seek an administrative inspection warrant. The scope under a Notice of Inspection is records, materials and equipment, and a physical inventory of

controlled substances on hand.

The facility decides how to respond, with its own counsel, not with the pharmacist. This document does not advise a registrant whether to consent, and a consultant pharmacist should not either. What the pharmacist owes the facility is that the decision is not being made for the first time by whoever happens to be at the desk. That means three things exist in advance: a named person who is called immediately, counsel identified before there is a reason to call them, and a standing instruction that nobody signs anything or answers substantive questions until that person is present.

What the pharmacist contributes on the day, if asked and if present: the records, in order, and nothing else. Section 10.3's discipline applies, and so does the rule about not speculating.

And the preparation that matters more than any of it. A facility whose perpetual inventory reconciles, whose biennial is on file, whose 222 and CSOS records account for their sequence, whose theft-and-loss reporting is current, and whose storage meets the physical standard has an uneventful inspection. Everything in Phases 2 and 5 exists for this.

PART SEVEN

The Long-Term Care Variant

PART 7 · THE LONG-TERM CARE VARIANT

What this part is for. Long-term care runs the same workflows on a different clock. The month replaces the visit as the unit of rhythm, the medication pass replaces the case as the unit of custody, and the regimen review becomes the centrepiece of the pharmacist’s work. Read Parts 1 through 5 first; this part carries only what changes.

Inside: what changes and what does not, the regulatory spine, the work itself, cadence and counterparts, the leadership summary, the emergency medication kit, and standing up a long-term care engagement.

7.0 What a long-term care facility is

The setting. A nursing facility is a residence, not a procedure site. Residents live there, often for years, and the people you serve are older, frailer, and on more medications than any other population you will encounter. Ten to fifteen chronic drugs per resident is normal. The building runs around the clock on a medication pass rhythm rather than a case schedule, drugs arrive from an outside long-term care pharmacy, and nursing staff administer them.

How it is governed, and how that differs from an ASC. The center of gravity moves to 42 CFR 483, and the difference matters immediately: where the ASC rule never mentions a pharmacist, 483.45 requires one explicitly. The facility must employ or obtain the services of a licensed pharmacist who consults on all aspects of pharmacy services, establishes controlled-drug records sufficient for accurate reconciliation, and confirms those records are in order. On top of that sits the requirement that defines the role: the drug regimen of every resident must be reviewed at least once a month by a licensed pharmacist, including a review of the resident’s medical chart, with irregularities reported in writing to the attending physician, the medical director, and the director of nursing, and those reports must be acted upon.

What that means for the work. The job is more clinical and more prescriptive than the ASC role. The monthly regimen review is the centerpiece, the unnecessary-drug and psychotropic rules give you a defined clinical mandate, and the survey process is tag-based, so your work is read against a specific citation map. Section 7.2 carries that map.

What surprises pharmacists coming from an ASC. The cadence is monthly rather than by visit interval, the unit of work is the resident rather than the case, the counterpart set widens to include the medical director and attending physicians, and your recommendations go to prescribers in writing and are tracked to a response. The custody discipline you learned in the ASC still applies; it is simply no longer the majority of the job.

7.1 What changes and what does not

The four layers hold. A standard, training, follow-through, and expertise are as load-bearing in a nursing facility as in a surgery center. What changes is the regulatory spine, the cadence, the central work product, and who the counterparts are.

Honesty first. This part is a working variant, not the full standard. The ASC standard in Layers 1 through 5 is specified to the phase and the form; the variant below is specified to the visit structure, the review method, and the survey lens, and it borrows the ASC form set rather than shipping its own. A pharmacist running LTC from this document has the structure and the method, and will adapt the record set against 42 CFR 483.45 and their state’s rules.

7.2 The regulatory spine

The center of gravity moves from 416 to 483.

42 CFR 483.45 requires the facility to provide routine and emergency drugs and biologicals, to employ or obtain the services of a licensed pharmacist, and it defines the two roles that structure all LTC pharmacy work:

The consultant role. The pharmacist provides consultation on all aspects of the provision of pharmacy services in the facility.

The drug regimen review. The drug regimen of each resident must be reviewed at least once a month by a licensed pharmacist, with irregularities reported in writing to the attending physician, the medical director, and the director of nursing, and those reports must be acted upon.

Two further anchors:

- **Unnecessary drug rules.** Each resident's regimen must be free from unnecessary drugs: excessive dose, excessive duration, without adequate monitoring, without adequate indication, or in the presence of adverse consequences indicating reduction or discontinuation.
- **Psychotropic rules.** PRN psychotropic orders are limited to 14 days. A prescriber who believes a longer duration is appropriate should document the rationale and indicate the duration, so the limit is a documentation trigger rather than a hard stop. PRN antipsychotics are the stricter case: they are limited to 14 days and cannot be renewed unless the prescriber evaluates the resident for the appropriateness of that medication.
- **Gradual dose reduction.** Residents on psychotropics receive documented dose-reduction attempts and behavioral interventions unless clinically contraindicated, with the contraindication documented. Surveyors read this under the psychotropic tag.

The survey lens. LTC surveys cite pharmacy work under a specific block of tags, and knowing the map changes how findings and reports are written, because it is the frame the surveyor is holding.

Tag	What it covers	Regulation
F755	Pharmacy services, procedures, the pharmacist, records	483.45(a), (b)(1)-(3)
F756	Drug regimen review, irregularities reported and acted on	483.45(c)(2), (4), (5)
F757	Regimen free from unnecessary drugs	483.45(d)(1)-(5)
F758	Psychotropic medications and the PRN limits	483.45(c)(3), (e)
F759	Medication error rate below five percent	483.45(f)(1)
F760	No significant medication errors	483.45(f)(2)
F761	Labeling and storage of drugs and	483.45(g), (h)

	biologicals	

Two consequences worth teaching. F756 is frequently cited in combination with F757 or F758: an unnecessary-drug deficiency doubles when the record shows the pharmacist never flagged it, which is why the regimen review documents what was considered, not only what was found. And the drug regimen review must include a review of the resident’s medical chart, per 483.45(c)(2), so an MRR run from the medication list alone is incomplete on its face.

State rules layer on top, exactly as in the ASC standard, and the Appendix A.3 method applies unchanged: establish the baseline for your state, in writing, with citations and dates.

7.3 The work itself

The MRR is the center. In an ASC, the visit examines a system. In LTC, the month's work is resident-by-resident clinical review at chart level, and the system review wraps around it.

A competent MRR per resident covers: the full regimen against indications; dose appropriateness for age and renal function; duplication; interactions; monitoring that is ordered and actually happening; unnecessary drug criteria; psychotropic appropriateness and gradual dose reduction status; and anything the nursing notes say that the orders do not reflect.

The review, as a sequence. Chart first, per the rule. Then the medication administration record against the orders. Then the labs and monitoring the regimen requires against what is actually being drawn. Then the nursing notes for the month, because the notes say what the orders do not: the falls, the refusals, the sedation, the behavior chart. Then the regimen itself against the unnecessary-drug criteria, one drug at a time, each with an indication that appears in the record. Psychotropics get the extra pass: indication, PRN status against the fourteen-day limits, and the dose-reduction history. Twenty minutes for a stable resident, longer for the ones the notes flag, and the notes flag them only if the notes were read.

What the written irregularity contains. The rule requires a separate written report to the attending physician, the medical director, and the director of nursing. Make it the LTC finding: the resident, the drug, the irregularity stated factually, the recommendation, the rule or criterion behind it, and the date. One irregularity per entry, actionable on its face. Section 1.6's discipline, wearing a different form.

Acted upon is the follow-through layer. Every report gets a response: accepted, declined with a documented clinical rationale, or unanswered, and unanswered is its own category with an aging clock on it. A physician may decline a recommendation, and a documented decline is a functioning system. A report with no response at all is the F756 citation writing itself, and a pattern of silence escalates to the medical director, in writing, because that is who the rule says also receives the reports.

Irregularities are reported in writing to the attending physician, the medical director, and the DON, and the report must be acted upon. That "acted upon" is the LTC version of follow-through: a report nobody responded to is a finding in itself, and surveyors read the response trail.

The system review still happens. Storage, labeling, controlled substances, emergency kits, medication carts, treatment carts, and destruction. Monthly at minimum. The eight-phase discipline from Part 1 adapts naturally: the phases compress, the completion conditions survive.

ASC phase	LTC monthly equivalent
1 Arrival	Arrival, postings, and what changed: admissions, discharges, deaths, order volume
2 Controlled substances	Cart counts, shift-count records, disposition for discharged and deceased residents, destruction
3 Storage	Med rooms, carts, treatment carts, refrigerators, every named location
4 Emergency equipment	Emergency kit or e-box, seals, and the crash cart where one exists

5 Ordering and returns	The dispensing-pharmacy interface: deliveries, returns, credits, the destruction path
6 Documentation	MAR audits, psychotropic and dose-reduction tracking, incident and error logs, policies
7 Walkthrough	A medication pass observed, and the building walked
8 Wrap-up	Debrief, the written reports issued, next visit scheduled

The MRR block sits in the middle of that structure and takes the largest share of the day.

Controlled substances differ in texture. The volume is lower than an ASC but the custody chain is longer: more hands, more shifts, more days. Counts at shift change, disposition records for discharged and deceased residents, and destruction with the state-required witnesses are where LTC discrepancies live.

The medication pass observation. The error-rate tags are surveyed by watching medication administration, and the facility's own program should watch first. Observe a pass periodically: right resident, right drug, dose, route, and time, against the orders, with the observed error rate calculated the way a surveyor calculates it, because the five percent line at F759 is measured, not felt. An observed pass also teaches more about the facility's real medication culture than a month of chart review.

The tools the review uses

A regimen review is a judgment, and judgment travels better when it is anchored to a named reference the facility and the prescriber both recognise. Two matter enough to name.

A published criteria set for potentially inappropriate medications in older adults. The widely used one is maintained by a professional geriatrics society and revised periodically. Its role is to structure the review, not to decide it: an entry on the list is a prompt to ask whether this drug is right for this resident, not an instruction to stop it. A recommendation that cites a current criteria set and then explains why it applies to this resident is harder to dismiss than one that reads as a preference, and a recommendation that cites the list and stops there deserves to be dismissed. Confirm the current edition rather than working from a copy of unknown vintage.

The facility's own psychotropic and dose-reduction expectations, which the survey process already applies. The review's job is to make the facility's existing obligation easier to meet rather than to introduce a parallel standard.

The discipline that keeps both useful: one recommendation with its rationale and its monitoring plan beats a list of flags. A prescriber who receives twelve items will action none of them, and the pharmacist who sent twelve has confused thoroughness with effect.

Antibiotic stewardship in long-term care

Nursing homes have their own national stewardship framework, separate from the outpatient one that 6i builds on, and unlike ambulatory surgery centers they are generally expected to have a program. The pharmacist's part is the same shape as 6i and the content differs.

- **The high-volume question is different.** In long-term care the recurring issue is treatment of suspected infection, particularly urinary, where the decision to treat is often made on a change in condition rather than on a confirmed diagnosis. Asymptomatic bacteriuria is the classic example of treatment without benefit.
- **What the pharmacist contributes** is the same three things: a written facility protocol derived from the current national framework, an audit of practice against that protocol with a rate and a denominator, and the reporting route into the facility’s quality program.
- **The review is the natural vehicle.** Antibiotic orders surface in the regimen review already, which makes the stewardship audit a byproduct of work the pharmacist is doing rather than a separate project.
- **The boundary is the same.** Treatment decisions for a resident belong to the prescriber. The pattern belongs in the report.

7.4 Cadence and counterparts

Monthly is the floor, set by the MRR requirement, and most facilities need the pharmacist on site more than the floor requires.

The counterpart structure shifts. The DON remains central. The medical director is a written correspondent every month rather than an occasional reader. The MDS coordinator matters because drug regimen review findings interact with assessments. And the facility’s dispensing pharmacy is a counterpart in a way an ASC’s wholesaler is not, because the consultant pharmacist and the dispensing pharmacy are usually different entities with different incentives, and the consultant’s independence from the dispenser is part of the value.

The Facility Pharmacy Lead concept transfers directly, and is even more consequential in LTC because medication administration happens around the clock. The curriculum in 3.1 adapts with the obvious substitutions: med pass observation replaces procedure-area observation, cart audits replace OR cabinet checks.

7.5 What the leadership summary becomes

The five questions from 6.4 survive with one addition: regimen review completion. The facility’s board and administrator need to see, monthly, that every resident’s review happened, what irregularities were reported, and whether the physicians responded. Completion, irregularity count, response rate, and aging of unresolved reports. Those four numbers are the LTC program’s pulse.

7.6 The emergency medication kit

The e-kit is the anesthesia box's sealed cousin: a small stock of controlled substances and dangerous drugs kept at the facility to cover the gap between an urgent order and the dispensing pharmacy's delivery. It is the one place in long-term care where drugs live on site without a resident's name on them, which is exactly why the rules around it are specific and why surveyors open it.

The structure, using Texas as the worked example. The kit belongs to a provider pharmacy, not to the facility: a community or institutional pharmacy within twenty miles, holding the Board's remote-services registration for emergency kits, whose pharmacist-in-charge is responsible for the kit's compliance. The facility holds a written contract with that pharmacy spelling out the services and each party's responsibilities. Outside Texas, the A.3 baseline finds the same three facts: who may place a kit, under what registration, and on what contract.

Contents are a committee decision, and the rule names you. The kit's contents are determined and recorded by the consultant pharmacist, the provider pharmacy's pharmacist-in-charge, the medical director, and the director of nursing together, limited to a prudent number of drugs sized to genuine emergency need, meaning situations where the dispensing pharmacy cannot supply in time. This is one of the few places in American pharmacy regulation where the consultant pharmacist appears by name, and the contents review is therefore yours to convene, not to wait for.

The cycle the visit verifies:

1. The kit is sealed, and the seal number on the kit matches the seal number on record. A kit checked by looking at it is not checked.
2. Every entry into the kit was for an order, was documented, and was notified to the provider pharmacy per the rule's notification requirement. The entry that nobody phoned in is the entry that becomes a variance at the pharmacy's next reconciliation.
3. After every entry, the pharmacy restocked and resealed, and the new seal number was recorded. The gap between entry and reseal is the kit's exposure window; it should be measured in days, not weeks.
4. The contents match the approved list, nothing is expired, and the list itself carries the four signatures and a review date within the year.
5. Inventories of the kit are taken the same day as the provider pharmacy's own, listed separately, so the kit's count and the pharmacy's records can actually be reconciled against each other.

Where it fails: the kit that became a convenience cabinet, opened for routine doses because delivery felt slow; the seal log nobody started; the contents list from the administrator before last; and the second kit from a second pharmacy nobody documented an agreement for. Each is a finding, and the first carries the most diversion exposure, because a kit opened casually is a controlled substance stock with little custody culture around it.

In TOM MMS the kit is a location like any other: entries record against it, the seal number fields carry the cycle, and the notification to the provider pharmacy is the one step that stays a phone call, because the rule says the pharmacy hears about every entry, not the software.

7.7 Standing up a long-term care engagement

Part 8 governs a building that does not exist yet. An LTC engagement usually starts inside a building that has run for years, with habits, backlogs, and a binder from the consultant before you. The standup is therefore an assessment and a repair sequence, not a construction sequence.

1. **The contracts, first.** Your consulting agreement, and the facility's contract with its dispensing pharmacy and its e-kit provider pharmacy, read before the first visit. The rule requires the e-kit contract to exist; experience says half the time nobody can find it. A missing or stale pharmacy contract is finding one, written on day one.
2. **The baseline, LTC edition.** The A.3 method, pointed at the nursing facility chapter: the state's pharmacy-services sections, the MRR requirement and its clock, the e-kit rule, and the federal survey tags in 7.2's map. One page, dated, in the engagement file.
3. **The first month is a census of the medication system.** Storage rooms and carts walked, the e-kit cycle from 7.6 verified, the dispensing pharmacy's delivery and crediting rhythm observed, the MRR completion history pulled for the trailing quarter, and the irregularity reports sampled for whether physicians actually respond. Write what is, before prescribing what should be.
4. **The MRR machine, made current.** Every resident, every month, per 7.3's method, with the completion arithmetic honest: a review documented without the chart open is not a review. If the backlog is real, the recovery plan is written, dated, and shared with the DON and medical director rather than quietly absorbed.
5. **The Lead, adapted.** The 3.1 curriculum with 7.4's substitutions, taught to the charge structure that actually exists across shifts, because medication administration here never stops and the day-shift champion model leaves nights and weekends uncovered.
6. **The reporting rhythm.** The 7.5 summary from month one, even when month one's numbers are ugly, because the trend line is the product and it needs a starting point.

The engagement is stood up when the contracts are current and findable, the baseline is written, the e-kit cycle verifies clean, the MRR completion number is true and trending, and the facility knows which four numbers the board will see every month.

PART EIGHT

Opening a New Center

PART 8 · OPENING A NEW CENTER

What this part is for. Standing up a program in a building that does not operate yet is a different job from improving one that does. There is no practice to observe, no record to read, and every decision made now becomes the habit the facility keeps. It is also the only moment when the pharmacist can design the program rather than repair it.

Inside: why this is its own part, what to establish before agreeing to the engagement, the licensing sequence with its dependencies and lead times, what the pharmacist builds before anyone is hired, standing up the program, the opening-day state, the first ninety days, what the engagement is worth, the handoff to steady state, and the physical layer including hardware choices.

8.1 Why this is its own part

Everything in Layers 1 through 5 assumes a facility that exists: staff who have habits, records with history, a cabinet with stock in it. A center under construction has none of that, and the consultant pharmacist's work is correspondingly different. It is also, done properly, the highest-leverage engagement in this document, because every control is cheaper to build than to retrofit and every habit is easier to set than to break.

This part is written as a sequence. The order matters, because several items have lead times measured in months and the ones that do are the ones that stop an opening.

8.2 Before you agree to the engagement

A new-center engagement can be the best work a consultant pharmacist does or the worst, and which one it becomes is largely decided before anything is signed. Ask these before quoting.

When is the target opening date, and who set it? A date set by a construction schedule, a lease, or an investor expectation is a date that will not move for a licensing timeline. A date set with the licensing sequence in front of somebody is a date you can plan against. If the answer is the first kind, 8.3's lead times are the conversation to have immediately rather than in month three.

Who else is already engaged, and who decides? An architect, a construction manager, an equipment planner, an accreditation consultant, and a management company may all already be involved, each with their own view of the medication room. Find out who resolves a disagreement between them, because you will generate one when you ask for a room that was drawn as a closet.

Has anything already been decided that cannot be undone? Plans stamped, equipment ordered, a lease signed on a building with no room for a proper drug storage area. You are not obliged to fix a decision made before you arrived, and you are obliged to say plainly what it will cost in workarounds for the life of the facility.

What is the case mix, honestly? The formulary, the emergency drugs, the storage design, and the controlled substance volume all derive from it. A center that says pain management and means pain management plus orthopedics has just changed its DEA exposure, its MH obligation, and its refrigeration requirement.

Who will be in the building every day? The Lead has to exist before opening, and in a facility that has not hired anyone that is a conversation about a job description rather than a person. If the answer is that everyone will share it, say now what section 3.1 says: a facility where everyone owns the routine has nobody owning it.

What happens after opening? A standup engagement that ends at opening day leaves a program with no operating cycle, which is the most expensive way to build one. Agree the transition to steady state at the start, per 8.9, so it is a planned handoff rather than an awkward conversation in month four.

The engagement this is not. You are not the project manager for the facility, not the licensing agent, and not the accreditation consultant unless you have separately agreed to be. Section 5.9's limits apply with more force here than anywhere else in this document, because a project with a deadline pulls everyone toward doing whatever is not being done.

8.3 The licensing sequence, and its lead times

The sequence below is typical. The specifics are state-dependent, and the first task in any new-center engagement is confirming the sequence for this state against the A.3 baseline.

1. **State facility license.** The ASC license itself, from the state health department or equivalent. Frequently requires plan review, a life-safety inspection, and an initial survey. The long pole in most states.
2. **State controlled substance registration**, where the state issues one. Usually cannot be applied for until the facility license exists, and the DEA registration cannot be applied for until the state registration exists, which is what makes this a sequence rather than a checklist.
3. **DEA registration.** Form 224 for a practitioner-type registration or the appropriate registrant class for the facility, at the specific address, in the correct business activity. Applied for only after the state layer is complete. Federal processing time is weeks to months and is not expeditable by wanting it to be.
4. **Accreditation survey.** Scheduled after the facility can demonstrate operations, sometimes with a Medicare deemed-status pathway that has its own sequencing quirks per accreditor.
5. **Medicare enrollment and state Medicaid**, where applicable, which depend on the accreditation or state survey outcome.

The planning consequence: counting backward from a target opening date, the controlled substance layer alone can consume a quarter. A center that wants to open in June and has not filed its state CS application by early spring has already moved its opening, it just does not know yet.

The whole sequence on one page. Lead times vary by state and by workload, so treat the ordering as fixed and the durations as local questions answered by the A.3 baseline. What does not vary is that each row depends on the one above it, and that the last three rows cannot be compressed by wanting them to be.

Working backward from opening day	Depends on	Cannot start until
Facility license application	Plans, policies, ownership documents	The entity exists and the space is defined
Space and storage design signed off	Facility license requirements, case mix	The case mix is real rather than aspirational
Policies and procedures written	Case mix, design, the jurisdictional baseline	You know what the facility will actually do
Pharmacy licensure or registration, where the state requires it	Facility license status, a named responsible pharmacist	The facility license is far enough along that the state will accept it
DEA registration	State controlled substance registration, where the state has one, and a physical address	The state registration exists; the order matters and reversing it wastes weeks
Wholesaler account and ordering	DEA registration, licenses, ownership	The registrations are issued, not

Wholesaler account and ordering credentials	DEA registration, licenses, ownership paperwork	The registrations are issued, not applied for
Ordering and receiving controlled substances	All of the above, plus commissioned storage	Everything above is complete
Staff hired and trained	A Lead designated, a curriculum, and stock to train on	There is something to train on
Drills run	Emergency stock present, staff hired	The carts are built
First case	All of it	All of it

Three ordering mistakes that cost weeks. Applying for DEA before the state controlled substance registration where the state requires its own. Ordering stock against a registration that has been applied for rather than issued. And designing the storage after the plans are stamped, which converts a drawing change into a construction change.

No stock arrives before the registrations exist. A center cannot take delivery of controlled substances without the DEA registration in hand, at that address, and a wholesaler will not ship against a promise. First stock is a date on the plan, driven by the registration dates, and it is later than anyone wants it to be.

8.4 What the pharmacist builds before anyone is hired

The policy manual, written for this facility. Not purchased, not inherited from a sister site, and not a template with the name changed. Written against the state’s rules, the chosen accreditor’s current standards, and the actual case mix planned. This is weeks of work and it is the foundation everything else sits on. A manual written properly here prevents the most predictable finding in an operating facility, which is a manual that describes somewhere else.

The formulary, from the case mix. What the planned procedures actually require: anesthesia preferences, emergency medications, reversal agents, antibiotics per the surgical profile, and the controlled substance list with projected volumes. Par levels set from projected case counts, reviewed after the first real quarter, because projections are always wrong in an instructive direction.

The medication storage design, on the plans. Where the drug room is, where the safe is anchored, where refrigeration lives and what monitors it, where anesthesia carts park and how they lock, and the walking path from storage to procedure room. Storage retrofitted after millwork is expensive. Storage moved on a drawing is free.

The security architecture. Who will have access to what, how access is granted, how it is revoked, and what records the system will produce. Decide now whether the facility will be able to answer “when was access last revoked, and for whom” because designing that answer into the building is trivial and adding it later is a project.

The emergency equipment specification. The crash cart contents list, the MH cart per current MHAUS guidance for the anesthetics planned, and the policy language 42 CFR 416.44(d) requires: equipment specified by the medical staff and governing body, appropriate to this patient population.

8.5 Standing up the program

Hire or designate the Pharmacy Lead before opening, and run the full 3.1 curriculum before the first case, not during the first month. A Lead trained on empty shelves learns without pressure. The same training after opening competes with a schedule.

Train the founding staff as a cohort. The opening team sets the culture that every later hire inherits. The curriculum is the same as 3.1, delivered to everyone who will touch a medication, with competency recorded per person from day one. A center that opens with documented competency never has to reconstruct it.

Commission the storage, and record the commissioning. This is the step most often skipped, and it is the one that determines whether the first year’s temperature record means anything. Commissioning is not switching the refrigerator on. It is establishing, and writing down, that each storage location holds its range under the conditions the building actually creates: doors opening, HVAC running as it will run, the room occupied. Do it before stock arrives, keep the record, and date it. A facility that can produce its commissioning record has an answer to the first question an investigator asks after an excursion, which is whether the unit was ever suitable.

Before stock arrives: temperature mapping or at minimum a monitored stabilization period for refrigeration, alarm checks, lock and access verification, and the labeling of every storage location against the policy’s named-location list. The named-location list starts complete here, which is a luxury no operating facility has. Start it on Form C-31.

Receive first stock as a controlled event. The first controlled substance delivery establishes the perpetual inventory from a zero baseline: every unit counted in, entered, and reconciled on day one. There will never be another day when the record and the shelf can agree this easily. Treat it as the founding audit, because it is.

Run the drills before the first case. MH response with the actual cart in the actual corridor, emergency medication access timed from the actual rooms, and a mock code that touches the medication path. A drill before opening finds problems that cost nothing to fix. The same problems found during a real event are the other kind.

8.6 The opening-day state

A center is ready, from the pharmacy program’s perspective, when:

- Every license and registration is issued, posted, and recorded with its expiration date
- The policy manual describes this facility and has been adopted by the governing body
- Every storage location is named, commissioned, and stocked per its list
- The perpetual inventory reconciles to the shelf, at zero variance, because it was founded that way
- Every staff member who touches a medication has documented, current competency
- The Pharmacy Lead is named, trained, and has a posted escalation path
- The emergency carts are sealed, logged, and drilled
- The MH cart carries a full treatment supply against the formulation actually stocked. Newer concentrated formulations change the vial count for a comparable total dose, and the policy must match what is on the shelf.
- The first visit under the Part 1 standard is scheduled

8.7 The first ninety days

The program’s job in the first quarter is to find out where the plan was wrong, because it was, somewhere.

Par levels get corrected against real case volumes. The verification cadence gets tested against real entry volumes. The storage design gets tested by real staff under real time pressure, and the workarounds they invent in week two are the design review. A workaround in an established facility is a finding. A workaround in week two is free information about the building, and the correct response is usually to change the process rather than the people.

Visit cadence during this period is weekly regardless of what the steady state will be, because the rate of change is highest and the habits being formed now are the ones the facility will keep.

At day ninety, run the onboarding baseline from 6.2 as if arriving fresh. The delta between the opening-day state and the day-ninety state is the first trend report, and the cycle in Part 6 starts from there.

8.8 What this engagement is worth

Said plainly, because it affects how the work is scoped and priced: a new-center engagement is not a visit contract. It is a build. The pharmacist who does it properly delivers a policy manual, a formulary, a storage design, a security architecture, a trained founding staff, a commissioned program, and a facility whose first survey is a retrieval exercise.

That is months of work, much of it before revenue exists, and it is worth stating in the engagement letter as what it is rather than being absorbed into a visit rate that was priced for steady state.

8.9 The handoff to steady state

The build ends when the cycle begins. The marker is explicit: the day-ninety baseline is complete, the gap list from it has owners and dates, and the cycle in Part 6 starts from there. From that day the center is an operating facility running the standard like any other, and this part of the document stops applying to it.

8.10 The physical layer

Hardware is chosen once and lived with for a decade, which is why this section exists in the part about building a center, and why an existing facility replacing a cabinet should read it too. Section 2e audits what is installed; this is how to decide what to install.

The principle. The record is the control. Hardware raises the floor under it by making unauthorized access harder, slower, or attributable, but no cabinet has ever reconciled itself. A facility that buys control and skips the record has bought a very expensive drawer; a facility that runs a disciplined record behind a modest lock has a program.

The control classes, honestly compared.

Class	What it actually buys	Where it falls short	Cost shape
Keyed lock plus paper log	A barrier and a record, and it satisfies the federal requirement for a securely locked, substantially constructed cabinet	Attribution is only as good as the log; keys copy, and a key tells you nothing about who opened it when	Lowest capital, highest labor
Shared-code keypad	Convenience, and no keys to lose	No attribution at all, because a shared code is nobody’s code; the code outlives staff turnover unless someone changes it	Low
Individually credentialed electronic lock	Attribution at the door, with an audit trail of who opened it and when, revocable the day someone leaves	Tells you the door opened, never what left; still requires the record for quantity	Moderate capital, low service
Passive lockbox with numbered tamper-evident seals	Evidence of entry between checks, which is what a tray or kit actually needs	Detects rather than prevents; only as good as the seal log	Very low
Vendor automated dispensing cabinet	Per-pocket access, per-user login, machine-generated discrepancy queue, and reporting; the strongest hardware-layer attribution available	Capital and annual service cost sized for hospitals; overrides erode the control; the facility’s own data can be hostage to the contract; and it still does not perform the pharmacist’s phases	Highest, with recurring service

The honest position on automated cabinets. They are excellent hardware and they are frequently oversold as compliance. What a center with a handful of storage locations usually needs is attribution and a worked record, and that is achievable with credentialed access, seals, and a disciplined record layer at a small fraction of the capital. Where volume, diversion history, or multiple satellites justify the cabinet, buy it, and then run every phase in this document anyway.

Recommended hardware for a facility running TOM MMS. The software is browser-based and deliberately undemanding, because equipment that must be purchased is equipment that delays a program.

Item	What to get	Why
Point-of-care device	A current tablet or laptop with a modern browser, mounted or on a rolling stand within arm's reach of the cabinet	The whole standard depends on the record being made where the work happens; a computer down the hall guarantees reconstruction
Network	Reliable facility wireless coverage at every storage location, with the device on a managed rather than a guest network	A dead spot at the cabinet becomes a paper workaround within a week
Barcode scanner, optional	A two-dimensional imager, wired or Bluetooth, able to read the codes on unit packaging	Faster and more accurate selection at the point of sign-out; optional because typed selection works
Label printer, optional	A small thermal label printer at the preparation surface	Beyond-use and syringe labeling per Topic 6 without handwriting
Temperature monitoring	A recording device per unit with minimum and maximum retention and, where the facility wants alerting, a monitored probe with an audible alarm and a documented response path	3e's monthly curve needs recorded data, and after-hours excursions need someone to know
Room conditions	A thermometer, and a hygrometer where humidity is monitored, placed where stock actually sits rather than by the door	3i is unverifiable without an instrument in the right place
Seals	Numbered tamper-evident seals in a controlled supply, issued rather than kept in an open drawer	Topic 4's seal discipline depends on the numbers being controlled
Printer and secure storage	A printer for reports, and a locked file location for anything printed that carries patient information	Paper generated by a compliant system still has to be handled compliantly

Questions to ask any hardware vendor before signing.

1. Whose record is the record, and can we export our own data, in a usable format, at any time and at contract end?
2. What does attribution actually mean here: does the system know who, or only that the door opened?
3. What happens during a network or power failure, and what is the documented fallback?
4. What is the service response time, and what does the facility do while a unit is down?

5. What is the total five-year cost including service, consumables, and the interface work, not the quoted capital?
6. What does the vendor require from us at survey, and can we produce the evidence without calling them?

TOM MMS is deliberately hardware-agnostic. It runs the record layer on a browser and any of the classes above can sit underneath it, which is the point: a facility should be able to raise its physical control without changing how the program is run, and should never be told its compliance depends on a purchase.

PART NINE

The Freestanding Emergency Variant

PART 9 · THE FREESTANDING EMERGENCY VARIANT

What this part is for. A freestanding emergency center runs the same workflows on a clock that never stops. There is no opening and no closing, so every daily ritual becomes a shift-change ritual, the pharmacy itself is separately licensed, and nothing is scheduled. Read Parts 1 through 5 first; this part carries only the differences.

Inside: what changes and what does not, the regulatory spine, the records on a clock that never stops, standing one up, the visit as adapted, and the antidote question, which is the one stocking decision this setting cannot borrow from an ambulatory center.

9.0 What a freestanding emergency center is

The setting. A freestanding emergency center is an emergency department that is not attached to a hospital. It is open twenty-four hours a day, every day, and that is a condition of its license rather than a business choice. Patients arrive unscheduled and undifferentiated, from a sprained ankle to a cardiac arrest, and the center either treats and discharges them or stabilizes and transfers them to a hospital. Nobody is admitted, because there are no beds to admit to.

Why it is a distinct variant. Two things separate it from a surgery center. First, nothing is scheduled, so there is no closing routine, no quiet period, and no natural moment when the day's records get reconciled. Every daily ritual becomes a shift-change ritual. Second, and more consequential for a pharmacist, the pharmacy is often real in the legal sense: in Texas, the pharmacy function inside a freestanding emergency center is licensed by the Board of Pharmacy as a Class F pharmacy, which attaches a pharmacist-in-charge, a formulary, floor-stock rules, and a defined record set to the room itself. That is a materially larger pharmacist obligation than an ASC medication room carries.

What that means for the work. The stock is broader and the acuity is higher: resuscitation drugs, antidotes, antibiotics, sedation agents, and a controlled-substance footprint that runs continuously rather than case by case. Section 9.2 carries the regulatory spine, and the antidote question later in this part carries the one stocking decision this setting cannot borrow from an ambulatory center.

A note on jurisdiction. Freestanding emergency centers are licensed under state law and the model varies considerably from state to state, including whether the state licenses them at all. Part 9 is written against the Texas framework because that is where it was developed. Use the Appendix A.3 method to establish your own state's requirements before applying it elsewhere.

9.1 What changes, and what does not

A freestanding emergency center runs the workflows this document has already taught, on a clock that never stops. The sign-out is the same sign-out, the witnessed waste is the same waste, the box logic rides along per patient encounter, and the temperature record simply never gets to close. If Part 7 is the monthly dialect, this is the continuous one. Read the ASC layers first; this part carries only the differences.

Three differences are structural. First, the clock: the building is required to operate twenty-four hours a day, seven days a week, so there is no opening and no closing, and every daily ritual becomes a shift-change ritual. Second, the pharmacy is real: unlike an ASC’s medication room, the pharmacy function inside a Texas freestanding emergency center is licensed by the Board of Pharmacy, which means a pharmacist-in-charge, a formulary, floor-stock rules, and pharmacy records requirements attach to the room itself. Third, the tempo: nothing is scheduled. The census arrives when it arrives, the crash usage is real usage, and the records discipline has to survive a resuscitation at three in the morning.

What does not change: the perpetual inventory logic, the witness standard, the amendment culture, the escalation spine, the finding lifecycle, the QAPI connection, and every form in Appendix C that does not assume a closing time.

9.2 The regulatory spine

Layer	What it requires	Where it lives
Facility license	Licensed by the Texas Health and Human Services Commission; one license per location; continuous 24/7 operation is a condition of the license itself	Health and Safety Code chapter 254; rules at 26 TAC chapter 509, administratively transferred from 25 TAC 131 in November 2024
Pharmaceutical services	The facility shall be licensed as required by the Board of Pharmacy, shall maintain pharmaceutical policies and procedures, and may contract pharmaceutical services under a clause holding contracted services to the same standards	26 TAC 509.50
The pharmacy itself	Class F pharmacy standards: pharmacist-in-charge designation, formulary maintained by a facility committee, floor-stock and medication-order structure, and the record set the class requires	22 TAC 291.151
Controlled substances	Federal registration at the location, with everything Part 6 and section 5d already carry	21 CFR, per Appendix A.2
Operational standards	Medical director, staffing and training, anesthesia, medical records, infection control, and the rest of the operational chapter, which is the standup checklist’s skeleton	26 TAC 509.44 to 509.66

The jurisdictional baseline method in A.3 applies unchanged: outside Texas, the same three questions find the equivalent chapter, the equivalent pharmacy class, and the equivalent operational standards before the first visit.

9.3 The records on a clock that never stops

Shift counts are the dialect of opening and closing. Two authorized people count at each shift change, on whatever shift pattern the facility runs, every day including the ones nothing happened. The count that gets skipped on a quiet night is the count that would have caught the variance, and a facility that counts only on eventful days has a record that proves exactly that.

The day still closes on paper. The doors never close; the record does. A defined records day, shift count to shift count, is what makes reconciliation possible at all, and the visit samples across that boundary deliberately: the handoff is where continuous operations tear.

Crash usage documents after stabilization, honestly. Nobody signs out midazolam mid-resuscitation, and the standard does not pretend otherwise. The record is made as soon as the patient is stable, marked as the late entry it truthfully is, with the true event time, per Topic 1’s rule. A record that looks contemporaneous with a code is the record an investigator disbelieves first.

Restock is immediate, not end-of-day. In a building where the next patient is unscheduled, a cart or box below par is a patient-safety condition, not a task for later. The restock records at the restock.

Temperatures never rest. The excursion at three in the morning gets its corrective-action note from the person who found it, not from the day shift reconstructing it. Continuous or logged monitoring per the facility’s method, with the excursion response from Topic 3 unchanged.

9.4 Standing one up: the deltas from Part 8

Part 8’s discipline governs; run its sequence and layer these differences in:

1. The facility license comes from the Health and Human Services Commission under chapter 509’s licensing subchapter, and the 24/7 operating condition shapes staffing and the records plan from day one.
2. The pharmacy licenses separately: the Class F application names the pharmacist-in-charge, and that designation is a real job with the room’s compliance attached to it, not a signature. Resolve who holds it, and on what schedule, before the license application, not after.
3. Federal registration follows the pharmacy, and section 5d’s authority rules apply: who signs orders, whose certificate, whose power of attorney.
4. The formulary is a committee product under the pharmacy class’s structure, sized to emergency practice, and the shortage exposure of emergency drugs makes Phase 3’s alternatives thinking a standup task rather than a later refinement.
5. Policies must cover the pharmaceutical services section’s requirements and the operational chapter’s adjacent standards, and the contract clause matters: services provided under contract are held to the same standards as services provided directly, in writing.
6. The routines initialize on the 24/7 pattern from day one: shift counts, the records day, immediate restock, continuous temperature coverage. A center that opens on ASC habits and converts later converts through a variance.
7. Opening-day state per Part 8, with one addition: the first shift handoff is rehearsed before the first real one, both shifts present, because the handoff is the seam this building lives on.

9.5 The visit, adapted

The eight phases run as written, with these emphases: Phase 1 verifies the facility license, the pharmacy license, and the current pharmacist-in-charge designation as three separate live facts. Phase 2 reads count continuity across shift boundaries and samples nights and weekends on purpose, and 2h's box logic applies per encounter. Phase 3 reviews the continuous temperature record with particular attention to who responded to off-hours excursions. Phase 4 carries more weight here than anywhere else in this document, because emergency equipment is the point of the building: usage frequency is real, and restock latency is the metric to trend. Phase 5 runs under the pharmacy's own license and authority chain. Phase 6 adds the chapter 509 policy set to the review. The walkthrough in Phase 7 is scheduled across a shift change deliberately, to watch the handoff happen rather than hear it described.

This part is complete for a facility when the shift-count record reads unbroken across every sampled boundary, off-hours events carry their own contemporaneous responses, the pharmacist-in-charge designation matches reality, and the visit record shows nights were sampled, not assumed.

In TOM MMS the workflows run unchanged, because the software never assumed a closing time: the same sign-out, waste, temperature, and cart records carry shift-pattern operations, and the late-entry flag does its honest work at night exactly as it does at midday.

9.6 The antidote question

An ambulatory surgery center stocks emergency drugs for the emergencies its own procedures create, and Phase 4 covers them. A freestanding emergency center stocks for whatever arrives at the door, and that is a different problem with a different method. It is also the clearest place in this document where the pharmacist's contribution is decisive, because nobody else in the building is going to build this list.

Antidotes fail in a specific way. They are used rarely, they expire quietly, some are expensive enough that stocking them feels wasteful, and the moment they are needed is the moment there is no time to obtain them. A facility can go years without touching a given antidote and then need it inside minutes. That combination is why availability is a stocking decision made in advance rather than a clinical decision made on the day.

The method, and it is a published one. National expert consensus guidance exists on which antidotes a facility providing emergency care should stock, in what quantity, and how quickly each must be available, and it sorts them by urgency: some must be immediately available where the patient is, others may sit in a pharmacy provided there is a reliable mechanism to get them there quickly, and a few need only be obtainable. A freestanding center has no pharmacy down the hall to lean on, so the middle category collapses into the first for anything time-critical. That is the single most important adaptation, and it is the pharmacist's job to say it out loud.

The consensus guidance also asks each facility to do its own hazard assessment, which is the part the pharmacist runs. What does this county actually present with. What industry or agriculture sits nearby. What is the transport time to the nearest facility that stocks what this one does not. A center twenty minutes from a tertiary hospital makes different decisions from one that is ninety minutes out, and the assessment is what turns a national list into this facility's list.

What the pharmacist does, step by step.

1. **Convene the decision.** The medical director, the nurse leader, and the pharmacist, with the current published guidance and the facility's own hazard assessment in front of them. The output is a written stocking list with a quantity and a location for each entry, and the reasoning recorded for anything the facility chose not to stock. That last part matters more than the rest: a deliberate decision not to stock something, written down with its rationale and its transfer plan, is defensible. Silence is not.
2. **Set quantities against a real scenario**, not a single dose. The question is how much is needed to treat one patient for as long as it takes to stabilise or transfer them, which for several antidotes is considerably more than one package.
3. **Place them by time criticality.** Anything needed within minutes lives where the patient is. Confirm this by walking it rather than by reading the list.
4. **Put them on the expiry cycle**, because this is the category most likely to expire unnoticed, and short-dated antidotes are a par-level and purchasing conversation before they are a waste number.
5. **Verify the retrieval**, not the presence. Ask a nurse on shift where a named antidote is. A stock nobody can find in the dark at three in the morning is not stocked in any sense that matters.
6. **Review it annually and on any change** in the facility's case mix, its surrounding hazards, or the published guidance.

Where it fails: the list inherited from a hospital with a pharmacy and never adapted to a building without one; quantities set at one package because that is what the invoice offered; antidotes stored centrally for tidiness rather than where the patient will be; and a list nobody has revisited since the facility opened, which is the same failure mode as the formulary in 6h and for the same reason.

The boundary. Which antidote to give, and when, is the treating clinician’s decision. Whether it is in the building at all is a decision somebody made months earlier, and this section is about making sure somebody made it deliberately.

In TOM MMS the antidote set is a location with a contents list, checks, and expiry dates like any other, which is what keeps a rarely-touched stock from becoming an unverified one.

PART TEN

The Profession

PART 10 · THE PROFESSION

What this part is for. Everything before this governs the work. This part governs the person doing it: independence and conflicts of interest, how protected information behaves in a consultant’s own files and on their own devices, the consultant’s own custody discipline, the engagement file, how a pharmacist’s own quality is reviewed, how a complaint is handled, and how this standard itself is maintained.

It applies to every setting in this document, and it is the part to read before signing a first engagement rather than after.

Inside: independence and conflicts, protected information, the consultant’s own hands, the engagement file, quality assurance of the pharmacist, complaints, and governance of the standard.

10.1 Independence, and conflicts of interest

The value of everything in this document rests on one fact: the consultant's findings are bought by nobody. Three rules protect it.

Fees are independent of outcomes. The fee is for the work, agreed in advance and in writing, and never contingent on a survey result, a finding count, a compliance score, or any other outcome the pharmacist's own judgment produces. A consultant paid more for fewer findings has been paid to stop looking, whatever the contract calls it. The same logic bars fees tied to product sales or referral volume of any kind.

Independence from the dispenser and the vendor. Part 7 states it for long-term care and it generalizes: a consultant whose judgment reviews a supplier's performance does not take compensation from that supplier. Vendor consideration beyond the trivial, meals at a conference are not the problem, is declined or disclosed to the facility in writing, and where a genuine dual role exists, the facility hears about it before the engagement, not after a finding touches it.

The arrangement where your name is on it and you are not. This field has a specific failure that deserves naming, because it is common enough that a new consultant will be offered it and may not recognise what they are being offered. A facility needs a consultant pharmacist for a licence, an accreditation standard, or a policy, and what it wants is the name rather than the work. Sometimes it is proposed openly as a low-cost arrangement. More often it arrives by drift: visits get shorter, then remote, then rescheduled, then skipped, and the reports keep being signed.

The test is simple and it does not depend on anyone's intent. **If your name appears as this facility's consultant pharmacist, the work behind it has to exist, and it has to be evidenced.** A signed report for a visit that did not happen as described is a false record with your name on it, and no fee is worth what that costs. The same applies to the softer version: a visit that happened but that you know was too brief to support what you signed.

If an arrangement drifts this way, say so early, in writing, and offer the fix rather than only the objection: a shorter cadence you can actually deliver, a narrower scope honestly described, or an ending. A pharmacist who reduces the scope and says so has done the professional thing. A pharmacist who keeps the scope on paper and reduces it in practice has done the other one.

Product recommendations carry their interests. When a consultant recommends a product they profit from, they say so, in writing, at the recommendation. This document practises the rule on itself: the standard names TOM MMS throughout because the standard and the software were built together and share an author who sells it. That interest is disclosed here, plainly, and the standard is written to stand without the software, on paper, per 1.8, so no facility's conformance ever depends on a purchase.

10.2 Protected information in the consultant’s hands

A.2.3 establishes what you are: a business associate of every facility whose records you touch. This section is how that status behaves in practice, in your own notes, on your own devices, after the engagement ends.

Minimum necessary, in your own files. Findings are written as patterns, not patients: the record cites the log line, the date, the location, and only carries a patient identifier when the finding cannot exist without one, and then that note is handled as PHI in full. The test is simple: could this finding be read aloud in a staff meeting? If not, the identifying detail belongs in the facility’s system, referenced from yours.

Devices and transport. Nothing identifiable leaves the building on a personal device or a personal account. Photographs of records go into the facility’s own system or not at all. Anything carried offsite is encrypted, and the engagement file’s PHI footprint is kept deliberately small, because the safest record to protect is the one you never took.

At the end. When an engagement ends, however it ends, records containing PHI are returned or destroyed per the Business Associate Agreement, the destruction documented, and Form C-32’s handover carries the facility’s own compliance record forward to whoever comes next.

If you discover a breach, yours or theirs, the facility hears about it without delay, on the BAA’s clock, in writing. Discovery starts duties; hoping does not pause them.

10.3 The consultant’s own hands

The person who audits custody keeps the cleanest custody in the building.

- Counts are performed with a facility witness, every time. A consultant alone with the controlled substance stock has created the exact condition this entire document exists to prevent, with themselves in the frame.
- The consultant never takes custody: no transporting stock between locations, no carrying waste to the receptacle alone, no “I’ll just drop this at the pharmacy on my way.” Movement is the facility’s, on the facility’s records, per 2i.
- Keys, codes, and badges are the facility’s grant, surrendered on request and at engagement end, and never shared or duplicated.
- Fitness is a professional duty: a pharmacist who is impaired does not practise that day, arranges coverage, and treats their own state with the same honesty this document demands of a variance. Where state law or a peer-assistance program creates duties, they are met, not managed.

10.4 The engagement file

Every engagement carries a file that could be handed to a reviewer, or a successor, without embarrassment. Its contents: the signed agreement with scope and fee terms, the executed Business Associate Agreement, the current certificate of professional liability coverage, the jurisdictional baseline from A.3, and, at the end, the completed C-32 handover. Two rules ride with it: fee terms live in writing before the first visit, and records are never hostage, the facility's compliance record is theirs on demand regardless of any billing dispute, because a consultant who withholds evidence of compliance has manufactured the facility's non-compliance.

How long you keep your own copy is a decision, not an accident. Your engagement file is not the facility's record, and it serves a different purpose: it is the evidence of what you did, which is the only thing that answers a question asked years later about a visit you no longer remember. Set a retention period deliberately, informed by your state's rules for professional records, your insurer's expectations, and the limitations periods that apply where you practise, and ask counsel rather than choosing a number that feels right. Then follow it, because a file kept inconsistently is worse than either extreme: the gap looks like a decision even when it was neglect.

Two practical rules while you hold it. Keep it to the minimum necessary under 10.2, because the safest record to protect is the one you never took. And if you are ever notified of a claim, an investigation, or a proceeding that touches an engagement, stop any routine destruction of anything related to it immediately and take instruction before doing anything else.

10.5 Quality assurance of the pharmacist

The program audits facilities; someone must audit the program’s pharmacists, and the method is the one this document already trusts: read the record.

Solo practice: the annual self-review in the staying-current cycle, two of your own visit records read cold, upgraded whenever possible with an exchange, your two records to a peer, theirs to you, calibrated against the severity case set in Appendix D.

Group practice: peer record review quarterly, two records per pharmacist, reviewer named and signed, drift findings treated exactly like facility findings, an owner, a date, and closure. The review looks for the same three failures every time: severity drift, close conditions signed that the record does not support, and findings aging without escalation.

Beyond the floor. Consultant pharmacists are not subject to peer review of their own visit records anywhere in this document’s regulatory spine. This standard applies to its own practitioners the same discipline it asks of facilities, because a standard whose authors exempt themselves from it is a marketing document.

10.6 Complaints

A facility that believes the consultant got it wrong has a path, and the path is written into the engagement: first to the pharmacist, in writing; unresolved, to the group’s principal or the solo pharmacist’s named peer reviewer; and always, without impedance, to the state board, whose complaint process exists for exactly this and is never discouraged, delayed, or conditioned. Complaints are recorded and closed like findings, because a profession that documents facility failures and buries its own has written its own severity case.

10.7 The standard itself

This document is versioned annually. The version and its revision date are on the cover, and the change record between versions is maintained by the author rather than published here, because a reader needs to know which version they hold, not what moved inside it. Input is invited from any pharmacist, facility, or surveyor who works under it, through the contact on the cover, and substantive proposals are dispositioned in the next version’s control entry, accepted or declined with reasons.

Conformance claims are earned by the record. A pharmacist or facility may describe practice as consistent with this Program, by version, when the visit records demonstrate the layer’s discipline: the phases run, the findings carry their five elements, and the close in 1.7 is signed only when its conditions are true. The claim names the version, because the standard moves. No certification, endorsement, or credential is implied by the claim or granted by this document, and the license terms on the cover govern reuse of the text itself.

APPENDIX A

The Rules This Standard Sits On

APPENDIX A · THE RULES THIS STANDARD SITS ON

What this appendix is for. The standard makes determinations; the rules make them binding. This appendix names the federal and state layers the work sits on, and gives the method for finding the equivalent rules in a state this document does not cover.

State detail is deliberately absent. A list of fifty states goes stale the month it is printed. The method does not.

A.1 How to use this appendix

This is the regulatory floor under the standard, stated plainly, with the citation next to each claim. It is current as of this document’s date. Rules change, and the annual review in A.4 exists because they do.

Nothing here is legal advice. Where a determination matters, the source is the current text of the rule and, where it is genuinely ambiguous, counsel or a written question to the issuing body.

A.2 Federal

A.2.1 The Medicare Conditions for Coverage

42 CFR 416.48, Pharmaceutical services. The ASC provides drugs and biologicals in a safe and effective manner, in accordance with accepted professional practice, under the direction of an individual designated responsible for pharmaceutical services. Blood and blood products are administered only by physicians or registered nurses. Orders given orally must be followed by a written order, signed by the prescribing physician. Adverse reactions are reported to the physician responsible for the patient and documented in the record.

42 CFR 416.44(d), Emergency equipment. Emergency equipment appropriate to the facility's patient population, specified by policy adopted by the medical staff and governing body, immediately available for use, and maintained by appropriate personnel.

42 CFR 416.43, QAPI. The ASC develops, implements, and maintains an ongoing, data-driven quality assessment and performance improvement program. Performance improvement projects are documented, including at minimum the reason for the project and a description of the project's results.

42 CFR 416.50, Patient rights, including the privacy and confidentiality provisions the pharmacy program touches whenever it handles records, and the requirement at 416.50(g) that the ASC comply with the HIPAA privacy and security rules.

42 CFR 416.54, Emergency preparedness. The emergency plan, tested by exercises at least annually, with training documented at least every two years. Cited in this standard because a properly documented MH drill can serve both the pharmacy program and this obligation.

A.2.2 Controlled substances

21 CFR 1304.11, Inventory requirements. A complete inventory of all controlled substances on hand, taken at least every two years, on any date within two years of the previous biennial inventory. The inventory records whether taken at opening or close of business. For Schedule I and II substances, an exact count or measure of the contents of each opened commercial container; for Schedule III, IV, and V, an estimated count unless the container holds more than 1,000 tablets or capsules, in which case an exact count. Per 1304.11(e)(6), the same physical count discipline extends through dispensers and other registrant classes.

21 CFR 1304.04, Record retention. Inventories and records maintained for at least two years from the date of the inventory or record, available for inspection at the registered location.

21 CFR Part 1305. DEA Form 222 and CSOS for Schedule I and II ordering, including the sequence, retention, and voiding rules the Phase 5 review works against.

21 CFR 1301.71 and following, Security. Substantial construction, controlled access, and the general obligation to provide effective controls against theft and diversion.

Theft and significant loss. Reported to the DEA per 21 CFR 1301.76(b), with written notice to the local DEA field division within one business day of discovery and DEA Form 106 filed electronically within forty-

five calendar days (paper no longer accepted since July 2023), and to the state per the state’s own rules, which differ on thresholds and timing. The standard’s position: the reporting analysis is documented every time, even when the conclusion is that no report is required.

A.2.3 HIPAA

The consultant pharmacist is a business associate of each facility whose records they touch. An executed BAA per facility is a prerequisite in 2.3, the workforce training obligation appears in the same table, and state analogues can be stricter than the federal rule. Texas HB 300 is the example this document uses; your state may have its own.

A.3 The state layer, and the method

A.3.1 Why a method rather than a summary

Fifty states, and material variation on almost every question that matters to this program: whether a consultant pharmacist is required at all, what the visit frequency floor is, whether the state issues its own controlled substance registration, what reconciliation cadence is required, who may witness destruction, and what a variance triggers.

A summary would be wrong for most readers by next year. A method is durable.

A.3.2 The sixteen questions

The jurisdictional baseline is a written document answering these, each with a citation and the date it was checked:

1. Does this state license ASCs separately, and under what chapter?
2. Which agency surveys them, and against what standards?
3. Does the state require a consultant pharmacist for an ASC, and at what frequency, with what deliverable?
4. Does the state require a pharmacist-in-charge or equivalent designation, and must it be posted?
5. Does the state issue its own controlled substance registration, and in what sequence relative to the DEA registration?
6. What controlled substance reconciliation or periodic inventory does the state require beyond the federal biennial?
7. What are the state’s storage and security requirements beyond 21 CFR 1301?
8. Who may possess keys or access credentials to controlled substance storage, by license type?
9. What does the state require for waste, returns, and destruction, including witness requirements by license type?
10. What are the state’s rules on medication preparation and beyond-use dating in a facility of this type?
11. What must be reported to the state board, on what timeline, for a controlled substance loss or discrepancy?
12. What are the state’s requirements for medication-related policies, and on what review cycle?
13. What training or competency requirements does the state impose on staff who handle medications?
14. Does the state have privacy law stricter than HIPAA that touches this work?
15. May the facility or its practitioners dispense or supply take-home medications, including a limited post-operative supply, and under what authority, quantity limits, labeling, and record rules?
16. What changed in the last legislative session that affects any of the above?

A.3.3 Sources, in order of authority

1. The statute

2. The board’s administrative rules
3. The board’s published guidance and newsletters
4. A written answer from the board to a written question
5. Everything else, which is context and never authority

A verbal answer from a board phone line is notes toward a written question, not an answer.

A.3.4 The two resolution rules

Where more than one authority speaks, the strictest applicable requirement governs. Federal, state, accreditor, and facility policy are cumulative, not alternative.

Where the state is silent, silence is not permission. The gap gets a documented professional judgment, and where the stakes warrant it, a written question to the board.

A.4 Keeping the baseline current

Annually at minimum, and after every legislative session in the state. Subscribe to the board’s newsletter, calendar the session end, and re-verify the sixteen answers. The baseline records its own review dates, which makes staleness visible instead of silent.

APPENDIX B

What This Document Does Not Cover

APPENDIX B · WHAT THIS DOCUMENT DELIBERATELY DOES NOT COVER

What this appendix is for. A standard that claims to cover everything is hiding its edges. This appendix names what is out of scope and why, so a reader knows where this document stops and something else has to start.

Scope discipline is part of the standard. These exclusions are decisions, not oversights, and each has a reason.

Compounding beyond immediate-use. USP 797 and 800 govern sterile and hazardous compounding, and an ASC that compounds has obligations this document does not address. The standard covers the immediate-use boundary and the discipline of knowing where it is. A facility past that boundary needs a compounding-specific program, and pretending this document is one would be a disservice.

Dispensing. An ASC that dispenses take-home medication in the retail sense has stepped into pharmacy licensure territory that is state-specific and outside this standard. Several states do permit a limited post-operative supply, in some states framed as a seventy-two hour supply, provided by the practitioner under specific authority, labeling, and record rules. Whether this facility may, and under what conditions, is baseline question 15, and a facility doing it lawfully owes those records the same discipline as everything else in this document. The specification of a dispensing program remains out of scope.

340B. Its own compliance universe, with its own audits.

Clinical anesthesia practice. How an anesthetic is chosen and conducted belongs to the anesthesia professional, and this standard does not direct it. That is a boundary on authority, not on contribution: the pharmacist is an interdisciplinary clinical resource and part of the decision team, and brings pharmacology to formulary choices, agent selection, shortage substitutions, compatibility and dosing questions, and new-agent adoption whenever the team is deciding. What this document does not do is script that collaboration. It covers where anesthesia medications are stored, documented, and accounted for.

Employment law and individual discipline. The standard documents patterns and hands them to facility leadership. What happens to an individual is the facility’s to decide with its own counsel.

Radiopharmaceuticals, investigational drugs, and research pharmacy. Specialized programs with their own rules.

Medical device and implant tracking, except where a device is also a medication.

Detailed state summaries. Deliberately, per A.3.1. The method ships; a fifty-state table would be stale before it printed.

APPENDIX C

The Paper Forms

APPENDIX C · THE PAPER FORMS

What this appendix is for. Every record this standard requires, as a form that works on paper. Nothing in the program depends on buying software, and this appendix is the proof of that claim.

Two sets. The point-of-care and cycle records, and the administrator’s set that carries the whole-facility layer. Adapt them, retitle them, and reproduce them freely.

C.1 What this appendix is

Forty forms. Together they are the minimum record set for running the standard on paper, and they are the same record set TOM MMS produces as data.

The forms fall into two sets: the point-of-care and cycle records (C-1 to C-32, and C-38 to C-40), and the administrator's set (C-33 to C-37), which is the paper version of the whole-facility layer in 5.5 and 6.6. The table below indexes C-1 to C-32; C-33 to C-40 carry their own sections after it.

Form	Record
C-1	Visit record and phase log
C-2	Since-last-visit review sheet
C-3	Finding record
C-4	Findings register
C-5	Controlled substance sign-out and running balance (per drug)
C-6	Controlled substance count and reconciliation
C-7	Variance investigation record
C-8	Verification queue worksheet
C-9	Biennial and periodic inventory record
C-10	Access roster and revocation log
C-11	Temperature log
C-12	Cart and box check log
C-13	Seal event record
C-14	Emergency drill record
C-15	Open findings register (carried forward)
C-16	CAPA record
C-17	Accepted risk record
C-18	Education session and attendance record
C-19	Competency record, per person
C-20	Pharmacy Lead designation and escalation path
C-21	Leadership summary template
C-22	Quality study record
C-23	Policy review log
C-24	Ordering and receiving reconciliation

C-25	Waste and witness log
C-26	Destruction and reverse distribution record
C-27	Incident and adverse reaction log
C-28	Daily controlled substance count sheet
C-29	Between-visit consultation log
C-30	Licensure and registration expiration tracker
C-31	Named storage location register
C-32	Facility handover record

C.2 Rules that apply to every form

- Ink, contemporaneous, attributable. Every entry carries who and when.
- Corrections are amendments: single line through the original, the correction beside it, initials and date on both. Nothing is obscured and nothing is rewritten.
- A blank field is filled with N/A or a dash, never left empty, because an empty field is indistinguishable from a skipped one.
- Retention per the facility’s schedule and never less than the federal floor for controlled substance records.
- The forms are templates. Reproduce, adapt, and re-title them freely.

C.3 The honest cost

Every form below works. Together they also constitute the manual workload this program’s software exists to remove: the carrying-forward, the cross-referencing, the counting, and the assembly. Run them on paper and the program functions. You will spend the difference in evenings, and the sections titled “Running this without software” throughout this document say where. With the administrator’s set and the operational records the count is forty forms, and that number is the honest statement of what a facility maintains by hand, or subscribes to have carried.

C.4 The workarounds, and what they cost

Every one of these appears in real facilities, none of them are done by bad people, and all of them are the same thing: a paper system meeting a schedule that does not pause for it. They are listed because a pharmacist who recognizes them on sight saves months, and because naming them is how a Lead learns to design them out rather than punish them.

The workaround	Why it happens	What it costs at survey, and after
Backfilling the log at the end of the day, one pen, one sitting	The turnover gap was three minutes and the cabinet is down the hall	Uniform ink and handwriting across a week is visible instantly, and it converts every entry into a reconstruction. A variance found later cannot be tied to a case or a person
Pre-signing the witness line, or a witness who signs without watching	Two people cannot always be free at the same moment	The witness signature is the entire control on waste. Once it is known to be ceremonial, the facility has no waste record at all, only a waste ritual
Carrying the count forward instead of counting	The count agreed yesterday and the schedule is full	Two offsetting errors, or a slow diversion, will survive indefinitely. The first real count then produces a variance nobody can date
One person holding both the count and the record	Staffing is thin, especially at the end of the day	Removes independent verification exactly where the standard requires it, and puts a single employee alone with an unverifiable number
Logging from memory after the case rather than at the point of care	Hands are gloved, the patient is on the table	Times drift, waste amounts round, and the record stops matching the anesthesia record. Two records that disagree are worse than one record
The temperature log filled in for the days nobody came	A weekend, a holiday, a closure day	Readings for a day the building was empty are false records, and a surveyor who finds one stops trusting the whole log
The sticky note on the cabinet, the number to be entered later	The tablet or binder was not where the work was	Notes are lost, and the entry that never got made is an unaccounted quantity of a controlled substance
Transferring stock between rooms as a hallway handoff	It is thirty feet away and both people are trusted	Two location balances are now wrong, and neither person can prove what moved
The seal log updated from memory at the end of the week	Seals are checked, but the log lives elsewhere	The seal record is the only proof of non-entry between checks; from memory it proves nothing
The correction made by writing over	The first entry was wrong and the	An altered controlled substance

The correction made by writing over the original entry	The first entry was wrong and the form has no space	An altered controlled substance record reads as concealment regardless of intent, and it is the fastest way for an honest error to become an investigation

The pattern under all ten is distance: distance between where the work happens and where the record lives, in feet or in minutes. Every one of these disappears when recording takes less time than working around it.

How the software answers each of them. Named plainly, because the honest-cost framing in C.3 is only honest if it says what the money buys.

The workaround	What TOM MMS does about it
Backfilling	Entries are timestamped when made, and an entry made later is marked as a late entry with the true event time recorded, so honesty is easier than reconstruction
Ceremonial witnessing	The witness is a second person’s own credential entered at the moment of save, not a line to sign afterward
Carrying counts forward	The expected balance is computed from the record, so a count is a comparison rather than an act of memory
Single-person control	Roles and credentials are distinct, and the count and the witness cannot be the same identity
Memory logging	The record is made at the cabinet on the device that is already there, in the same seconds the drug is pulled
False temperature entries	Readings attach to the date they were entered, and out-of-range readings hold the save until a corrective note exists
Sticky notes	There is nothing to transcribe later, which is the only reliable fix for a note
Hallway transfers	Every entry names its location, so movement has to be recorded as movement
Seal logs from memory	The seal number is entered against the check at the check
Overwriting an entry	Records amend rather than overwrite, with the original preserved and the amendment attributed, which is what turns an error into a documented correction

None of this replaces the pharmacist, and the standard’s position in 1.8 stands: paper works, and every control above then depends on someone remembering. What the software removes is the reason to work around it.

C.5 The forms

APPENDIX C

The Forms

Visit record and phase log

Appendix C · Form C-1

FACILITY _____ DATE _____

PHARMACIST _____ ARRIVED _____ DEPARTED _____

VISIT TYPE ☐ Routine ☐ Follow-up ☐ For cause ☐ Baseline

PRE-VISIT REVIEW COMPLETED ☐ Yes ☐ No (attach C-2)

OPEN FINDINGS REVIEWED ☐ Yes ☐ No (from the open findings register, C-15)

PHASE LOG

Phase Status Time Notes/ref

1 Arrival & administration ☐ C ☐ NA ☐ Issue ___ _____

2 Controlled substances ☐ C ☐ NA ☐ Issue ___ _____

3 Storage areas ☐ C ☐ NA ☐ Issue ___ _____

4 Emergency equipment ☐ C ☐ NA ☐ Issue ___ _____

5 Ordering & returns ☐ C ☐ NA ☐ Issue ___ _____

6 Documentation ☐ C ☐ NA ☐ Issue ___ _____

7 Walkthrough ☐ C ☐ NA ☐ Issue ___ _____

8 Wrap-up & reporting ☐ C ☐ NA ☐ Issue ___ _____

C = complete. Any phase skipped: reason and pick-up date in Notes.

Any Issue: finding record (C-3) number in Notes.

FINDINGS THIS VISIT: C-3 numbers _____

DEBRIEF HELD WITH _____ ROLE _____

NEXT VISIT SCHEDULED FOR _____

NARRATIVE SUMMARY (2-5 sentences)

_____

_____

_____

SIGNATURE _____ DATE/TIME SIGNED _____

Submit within 24 hours of departure.

Since-last-visit review sheet

Appendix C · Form C-2

FACILITY _____ PERIOD _____ to _____

COMPLETED BY _____ DATE _____

CONTROLLED SUBSTANCE ACTIVITY

Entries recorded ____ Awaiting verification ____

Past verification window ____ Discrepancies open ____

TEMPERATURE

Readings expected ____ Recorded ____ Gaps ____

Excursions ____ Excursions with corrective action ____

CARTS AND BOXES

Checks expected ____ Recorded ____ Gaps ____

Seal events since last visit ____ (C-13 refs) _____

EDUCATION delivered since last visit ☐ None ☐ Sessions: ____

INCIDENTS since last visit ☐ None ☐ Count: ____

STAFF CHANGES touching medications ☐ None ☐ Detail below

POLICY CHANGES ☐ None ☐ Detail below

EXPIRATIONS INSIDE 90 DAYS (licenses, registrations, certificates)

NOTES

Finding record

Appendix C · Form C-3

FINDING NO. _____ FACILITY _____ DATE _____

RECORDED BY _____ PHASE ___

WHAT WAS OBSERVED (factual, specific, dated)

WHY IT MATTERS (rule / standard / policy, cited; or professional judgment, stated as such)

SEVERITY ☐ Critical ☐ Important ☐ Informational

If Critical: communicated in person to _____ at _____

OWNER (named person or role) _____

DUE DATE (agreed at debrief) _____

STATE ☐ Open ☐ In progress ☐ Evidence submitted

☐ Closed ☐ Reopened (recurrence of no. _____)

☐ Accepted risk (complete C-17)

EVIDENCE OF CLOSURE (what was reviewed, when, by whom)

CLOSED BY (pharmacist) _____ DATE _____

Findings register

Appendix C · Form C-4

FACILITY _____ PAGE ___ of ___

No.	Date	Phase	Severity	Summary	Owner	Due	State

One line per finding. Full detail lives on C-3.

Controlled substance sign-out and running balance (per drug)

Appendix C · Form C-5

FACILITY _____ SHEET NO. ____ of ____

DRUG _____ STRENGTH _____ FORM _____

SCHEDULE ___ LOCATION _____

BALANCE FORWARD (from sheet no. ____) _____

Date/ time	Patient ID	Ordering physician	Recv'd (+)	Given	Wasted	Wit (init)	Ret'd	Balance	By (init)

BALANCE CARRIED to sheet no. ____ : _____

One drug and strength per sheet. Entries at the time of the event, in the hand of the person who did it. Waste is witnessed at the moment, in the witness's own initials. The balance runs line by line and is verified against a physical count on the daily sheet (C-28) and at the pharmacist's reconciliation (C-6).

Controlled substance count and reconciliation

Appendix C · Form C-6

FACILITY _____ DATE _____ TIME _____

COUNTED BY _____ WITNESS _____

COUNT METHOD ☐ Blind (record before comparing) ☐ Other: ____

LOCATIONS COUNTED (all that hold controlled substances)

☐ Main safe ☐ Anesthesia carts ☐ OR cabinets ☐ Boxes

☐ Quarantine/awaiting destruction ☐ Other _____

Drug / strength	Sch	Expected	Counted	Variance	C-7 ref	Counted by	Witness

Schedule II counted exactly, including partials.

ANY variance, any size: C-7 opened before investigation begins.

RECONCILIATION RESULT ☐ All balanced ☐ Variance(s), C-7 nos: ___

PHARMACIST SIGNATURE _____ DATE/TIME _____

Variance investigation record

Appendix C · Form C-7

VARIANCE NO. _____ FACILITY _____ DATE FOUND _____

DRUG _____ STRENGTH _____ SCHEDULE ___

DOCUMENTED BEFORE INVESTIGATION ☐ Yes (sequence rule: observe, then explain)

EXPECTED _____ COUNTED _____ VARIANCE _____

WINDOW: last verified balance date _____ to _____

WHO HAD ACCESS DURING WINDOW (names/roles)

RECORDS PRESERVED (nothing altered) ☐ Confirmed

INTERVIEWS (who, when; factual notes on separate sheets)

CAUSE DETERMINATION

☐ Documentation error (both the count AND the record findings persist)

☐ Process failure (CAPA no. _____)

☐ Loss/theft suspected or established

☐ Undetermined

REPORTING ANALYSIS (completed every time, even if conclusion is "not required"; cite the state rule and the federal rule considered)

DEA Form 106 filed ☐ Yes _____ ☐ Not required, analysis above

State report filed ☐ Yes _____ ☐ Not required, analysis above

RESOLUTION AND CORRECTIVE ACTION

PHARMACIST _____ DATE _____

FACILITY LEADERSHIP NOTIFIED _____ DATE _____

Verification queue worksheet

Appendix C · Form C-8

FACILITY _____ DATE _____ PHARMACIST _____

QUEUE AT START: total ____ Sch II ____ Past window ____

Worked in risk order: Schedule II first, then other schedules, oldest first within each.

Entry ref Drug/strength Verified against source Result

_____ _____ ☐ Yes ☐ OK ☐ Finding: ___

_____ _____ ☐ Yes ☐ OK ☐ Finding: ___

_____ _____ ☐ Yes ☐ OK ☐ Finding: ___

_____ _____ ☐ Yes ☐ OK ☐ Finding: ___

_____ _____ ☐ Yes ☐ OK ☐ Finding: ___

QUEUE AT END: total ____ BACKLOG REMAINING ____

Backlog documented as finding no. _____ (backlog honestly reported is a functioning program)

Verify only what was actually reviewed.

PHARMACIST SIGNATURE _____ DATE/TIME _____

Biennial and periodic inventory record

Appendix C · Form C-9

FACILITY _____ REGISTERED ADDRESS _____

INVENTORY TYPE ☐ Federal biennial ☐ Annual (TOM practice)

☐ Semiannual ☐ Other: _____

DATE _____ TAKEN AT ☐ Opening of business ☐ Close of business

PRIOR BIENNIAL DATE _____ (biennial due within 2 years of this)

Drug / strength / form	Sch	Count	Exact or estimated	Container status

Schedule I and II: exact count, including opened containers.

Schedule III-V: estimate permitted unless container >1,000 tablets or capsules, then exact.

RETAINED AT REGISTERED LOCATION ☐ Yes RETENTION: 2 years minimum

TAKEN BY _____ WITNESS _____

PHARMACIST SIGNATURE _____ DATE _____

Access roster and revocation log

Appendix C · Form C-10

FACILITY _____ STORAGE/SYSTEM _____

CURRENT ACCESS

Name	Role	Granted	By	Method

REVOCATIONS

Name	Revoked	By	Reason	Verified

LAST REVOCATION DATE _____ (a facility that has never revoked access has never tested that it can)

REVIEWED AGAINST CURRENT STAFF LIST BY _____ DATE _____

Temperature log

Appendix C · Form C-11

FACILITY _____ UNIT _____

ACCEPTABLE RANGE _____ (units: ___) PER POLICY NO. _____

CADENCE ☐ Once daily ☐ Twice daily ☐ Other: _____

Date	Time	Reading	In range?	If NO: corrective action	Init

OUT-OF-RANGE STEPS: record it; note duration if known; quarantine affected stock; notify Lead, then pharmacist same day if a temperature-sensitive drug is involved; document the corrective action; pharmacist determines usability. A blank corrective action column is the finding.

THERMOMETER/PROBE CALIBRATION: last date _____ ref _____

Cart and box check log

Appendix C · Form C-12

FACILITY _____ CART/BOX _____

LOCATION ASSIGNED _____

CONTENTS LIST VERSION/DATE _____

Date Seal no. Seal intact? Contents per Defib/equip Init

			list (if open check)	checks (if applicable)	

Record the seal number every check. A broken or mismatched seal:

stop, complete C-13, full internal check before resealing.

Seal event record

Appendix C · Form C-13

FACILITY _____ CART/BOX _____

DATE FOUND _____ FOUND BY _____

OLD SEAL NO. _____ CONDITION ☐ Broken ☐ Missing ☐ Mismatch

REASON (if known: code event, drill, restock, unknown)

FULL INTERNAL CHECK COMPLETED ☐ Yes BY _____ DATE _____

DISCREPANCIES FOUND ☐ None ☐ Yes: C-3/C-7 refs _____

RESTOCKED ITEMS _____

NEW SEAL NO. _____ APPLIED BY _____ DATE _____

PHARMACY LEAD NOTIFIED _____ PHARMACIST NOTIFIED _____

Emergency drill record

Appendix C · Form C-14

FACILITY _____ DATE _____

DRILL TYPE ☐ Malignant hyperthermia ☐ Code/emergency access

☐ Diversion response ☐ Other: _____

SCENARIO (one line) _____

PARTICIPANTS (name/role)

TIMED ELEMENTS

Element	Target	Actual

WHAT WENT WRONG (a drill where nothing went wrong was not a drill)

FINDINGS OPENED (C-3 nos.) _____

COUNTS TOWARD 416.54 EXERCISE ☐ Yes ☐ No

LED BY _____ SIGNATURE _____ DATE _____

Open findings register (carried forward)

Appendix C · Form C-15

FACILITY _____ AS OF DATE _____

CARRIED FORWARD BY _____

Sorted by AGE, oldest first. Age is the follow-through signal.

No.	Opened	Age(d)	Sev	Summary	Owner	Due	State

OVERDUE ITEMS FLAGGED ABOVE: count ____

RECURRENCES THIS PERIOD (reopened, not new): nos. _____

ACCEPTED RISKS ON REGISTER: nos. _____ (review dates current?)

CAPA record

Appendix C · Form C-16

CAPA NO. _____ FACILITY _____ DATE OPENED _____

TRIGGER ☐ Second occurrence of finding no(s). _____

☐ Severity warrants systems change

☐ Variance investigation (C-7 no. _____)

PROBLEM STATEMENT (what keeps happening)

ROOT CAUSE (why it happens; ask why until the answer is a system, not a person)

CORRECTIVE ACTION (fixes this instance)

PREVENTIVE ACTION (changes the system so it stops recurring)

OWNER _____ DUE _____

EFFECTIVENESS CHECK: how will we know it took? _____

CHECK DATE _____ RESULT _____

PHARMACIST SIGNATURE _____ DATE CLOSED _____

Accepted risk record

Appendix C · Form C-17

FINDING NO. _____ FACILITY _____ DATE _____

THE RECOMMENDATION (what the standard/pharmacist recommended)

THE DECISION (what the facility decided instead)

DECISION-MAKER (name and role) _____

STATED REASON (in their words)

PHARMACIST NOTE (risk as the pharmacist sees it, for the record)

REVIEW DATE _____ (appears in every quarterly review until withdrawn or corrected)

DECISION-MAKER SIGNATURE _____ DATE _____

PHARMACIST SIGNATURE _____ DATE _____

Education session and attendance record

Appendix C · Form C-18

FACILITY _____ DATE _____ DURATION _____

TOPIC _____

DRIVEN BY (finding/recurrence/study ref, if targeted) _____

DELIVERED BY _____

METHOD ☐ At the cabinet/point of use ☐ Classroom ☐ Other

CONTENT OUTLINE (what was actually taught)

_____

_____

ATTENDEES (name, role, signature)

_____

_____

_____

COMPETENCY DEMONSTRATED THIS SESSION ☐ Yes, recorded per person on C-19 ☐ No, knowledge session only

Competency record, per person

Appendix C · Form C-19

NAME _____ ROLE _____ HIRE DATE _____

FACILITY _____

Topic Demonstrated (not attended) Date By

1 CS logging (all entry types) ☐ Yes ____ ___

2 Witnessing ☐ Yes ____ ___

3 Temperature logging ☐ Yes ____ ___

4 Cart and box checks ☐ Yes ____ ___

5 Expired/beyond-use dating ☐ Yes ____ ___

6 Labeling and pre-drawn meds ☐ Yes ____ ___

7 Diversion awareness ☐ Yes ____ ___

8 Discrepancy response ☐ Yes ____ ___

9 Working with the pharmacist ☐ Yes ____ ___

10 Survey readiness ☐ Yes ____ ___

11 Anesthesia box reconciliation ☐ Yes ____ ___

ANNUAL REFRESH DATES _____

NEW HIRE: trained before touching medications ☐ Yes DATE _____

Pharmacy Lead designation and escalation path

Appendix C · Form C-20

FACILITY _____ EFFECTIVE DATE _____

PHARMACY LEAD _____ ROLE _____

DEPUTY _____ ROLE _____

(Deputy completes the same curriculum. Rotation weeks: ___ / ___)

THE ROLE OWNS: daily routine and its records; noticing and escalating gaps; new staff learn deliberately; visit readiness; facility-owned findings progress; supplies and forms exist.

THE ROLE DOES NOT OWN: pharmacist judgment; compliance determinations; discrepancy decisions beyond document-and-escalate.

ESCALATION PATH (posted where the Lead works)

Situation Call first Then

CS discrepancy (any size) Pharmacist + PIC Immediately

Suspected diversion Pharmacist + DON Immediately (not the colleague)

Temp excursion, sensitive drug Lead acts Pharmacist same day

Expired stock in active location Lead quarantines Pharmacist next contact

Med error / adverse reaction Facility process Pharmacist same day

Survey/inspector arrives Administrator Pharmacist immediately

Unsure Pharmacist Uncertainty is sufficient

PHARMACIST DIRECT LINE _____

DON SIGNATURE _____ LEAD SIGNATURE _____ DATE _____

Leadership summary template

Appendix C · Form C-21

FACILITY _____ PERIOD _____ to _____

PREPARED BY _____ DATE _____

(One page. Two at most. Written for a board, not a pharmacist.)

1. WHAT WAS REVIEWED

Visits conducted ____ Areas examined _____

Staff trained ____

2. WHAT WAS FOUND

Critical ____ (named below) Important ____ Informational ____

Critical findings, plainly:

---

3. WHAT WAS FIXED

Closed with evidence accepted ____ Notable closures:

---

4. WHAT REMAINS OPEN

Open ____ (prior period ____) Overdue ____

Accepted risks (named decision-makers): _____

5. WHERE THE PROGRAM IS GOING

Trend vs prior period: _____

The one or two things that matter most next:

Every number carries its denominator. No abbreviation without expansion. No citation without a plain-language sentence.

Quality study record

Appendix C · Form C-22

FACILITY _____ PERIOD _____ to _____

ACCREDITOR FRAMEWORK/VERSION USED _____

(Confirm the current template and step count before designing.)

REASON FOR THE PROJECT (federal minimum element)

MEASURE (defined before collection)

WHAT NUMBER MEANS THE INTERVENTION WORKED _____

BASELINE: value _____ collected _____ to _____ method ____

INTERVENTION (what changed)

REMEASURE: value _____ collected _____ to _____ same method ☐

RESULTS DESCRIPTION (federal minimum element; report what actually happened, including no improvement)

NEXT (especially if no improvement)

PHARMACIST _____ DATE _____

Policy review log

Appendix C · Form C-23

FACILITY _____

ACCREDITOR _____ STANDARDS VERSION _____

Policy Reviewed Against Result By/date

date (version)

_____ _____ _____ ☐ Current _____

☐ Revised

☐ Gap: ___

_____ _____ _____ ☐ Current _____

☐ Revised

☐ Gap: ___

_____ _____ _____ ☐ Current _____

☐ Revised

☐ Gap: ___

ANNUAL REVIEW COMPLETE ☐ Yes DATE _____

POLICY DESCRIBES ACTUAL PRACTICE, VERIFIED BY WALK ☐ Yes

Gaps between policy and practice: which side is wrong? _____

Ordering and receiving reconciliation

Appendix C · Form C-24

FACILITY _____ PERIOD _____ to _____

DEA FORM 222 / CSOS SEQUENCE

Forms in sequence _____ to _____ Voided (retained) _____

Missing numbers ☐ None ☐ Nos: _____ (finding: C-3 no. ___)

CSOS certificate holder _____ Current employee? ☐ Y ☐ N

RECEIVING (th Invoice ref	ree records that Drug/strength	should agr Invoiced	ee) Received	Entered	Match?

Delays arrival-to-entry beyond policy: _____

Received but never entered ☐ None ☐ Detail: _____

COMPLETED BY _____ DATE _____

Waste and witness log

Appendix C · Form C-25

FACILITY _____

Waste occurs at the time of the event, witnessed at the time.

Date/ time	Drug/strength	Qty wasted	Reason	Wasted by (sig)	Witness (own sig)	Witness saw it?

A witness signs for what they personally observed, in their own hand, at the moment. Credentials are never shared. Unwitnessed waste: reason documented, flagged to pharmacist, pattern review.

Destruction and reverse distribution record

Appendix C · Form C-26

FACILITY _____ RECORD OPENED _____

(An open destruction record ages visibly. Aging drafts are findings.)

METHOD ☐ Reverse distributor ☐ On-site per state rule

REVERSE DISTRIBUTOR _____ DEA NO. _____

Drug/strength	Qty	From (location/ quarantine ref)	Quarantined since

WITNESSES (per state r	ule; license types verified)

MANIFEST/RECEIPT REF _____ DATE SHIPPED/DESTROYED _____

PERPETUAL INVENTORY UPDATED (C-5) ☐ Yes

RECORD CLOSED DATE _____ PHARMACIST _____

Retention: per schedule, never below the federal floor.

Incident and adverse reaction log

Appendix C · Form C-27

FACILITY _____ PERIOD _____ to _____

Date	Type (error/ADR/ near miss/other)	Patient ref	Physician notified*	Corrective action	Documented in record*	Y date
___	_____	_____	☐ Y	date__	☐ Y	_____
___	_____	_____	☐ Y	date__	☐ Y	_____
___	_____	_____	☐ Y	date__	☐ Y	_____

*Adverse reactions: reported to the physician responsible for the patient AND documented in the record. Both halves, per 416.48.

ZERO INCIDENTS THIS PERIOD? ☐ Yes: reviewed for reporting suppression rather than assumed safe. Reporting culture note:

_____

REVIEWED BY PHARMACIST _____ DATE _____

Daily controlled substance count sheet

Appendix C · Form C-28

DAILY CONTROLLED SUBSTANCE COUNT

FACILITY _____ DATE _____

Count against the running balance on each drug's C-5 sheet.

Drug / strength	Bal per record	OPENING Count	COUN By	T Wit	CLOSING Count	COUN By	T Wit	Var	C-7 ref

Two people where facility policy requires two. Count the drug, then read the record, in that order.

ANY variance, any size: stop. Do not alter anything. Open C-7, notify the pharmacist and PIC immediately. (Handout D-17.)

ALL BALANCED ☐ Opening ☐ Closing

COMPLETED BY _____ WITNESS _____

This is the facility’s shift and day count. The pharmacist’s visit reconciliation is C-6, and the two are not substitutes for each other.

Between-visit consultation log

Appendix C · Form C-29

FACILITY _____ PERIOD _____ to _____

Anything advised between visits that changes what the facility does is recorded here, per 5.3. Same day for controlled substances, diversion, patient safety, or an active survey; one business day for everything else.

Date/ time	Raised by (name, role)	Question / situation (one line)	Advice given (one line)

For each line: Changes practice? ▢ Y ▢ N If Y: finding/CAPA/ policy ref _____ Pharmacist initials ___

A verbal recommendation that later matters and exists nowhere is the same defect as an undocumented finding.

Licensure and registration expiration tracker

Appendix C · Form C-30

FACILITY _____ REVIEWED _____ BY _____

Item Identifier Holder/ Expires Renewal Owner Started?
/ number address lead time

Facility license _____ _____ _____ _____ ___ ☐

DEA registration _____ _____ _____ _____ ___ ☐

(address matches THIS building? ☐ Y ☐ N)

State CS registration _____ _____ _____ _____ ___ ☐

Accreditation certificate _____ _____ _____ _____ ___ ☐

CSOS digital certificate _____ _____ _____ _____ ___ ☐

(holder still employed here? ☐ Y ☐ N)

PIC / responsible-
individual designation _____ _____ _____ _____ ___ ☐

Other: _____ _____ _____ _____ _____ ___ ☐

ANYTHING INSIDE 90 DAYS is flagged at every visit (Phase 1) and carries a named owner. A lapse stops the facility, and it lapses on a date nobody diarised because the person who filed it left.

Named storage location register

Appendix C · Form C-31

FACILITY _____ AS OF _____

A location nobody named is a location nobody audits. Every place a medication lives is on this list, and Phase 3 walks this list.

Location name Area Type (safe/cabinet/ Holds Security Access per

		cart/box/fridge/ freezer/other)	CS?	method	C-10 roster

ADDED this period: _____ by _____ date ____

RETIRED this period: _____ by _____ date ____

Medication found OFF this list is a finding before its contents are examined (Phase 3a).

REVIEWED AGAINST A PHYSICAL WALK ☐ Yes BY _____ DATE ____

Facility handover record

Appendix C · Form C-32

FACILITY _____ HANDOVER DATE _____

OUTGOING PHARMACIST _____

INCOMING PHARMACIST _____

The incoming pharmacist should be able to start from this record alone. If a handover requires a phone call, the record was insufficient (5.7.4).

CADENCE: interval _____ next visit scheduled _____

OPEN FINDINGS: count _____ register attached (C-15) ☐

Oldest open: no. _____ age _____ why it is still open:

RECURRENCES with open CAPAs: nos. _____ (C-16s attached ☐)

ACCEPTED RISKS: nos. _____ next review dates _____

WHAT HAS BEEN TRIED AND FAILED (so it is not tried again cold)

THE PEOPLE

Administrator _____ notes _____

DON _____ notes _____

Pharmacy Lead _____ deputy _____ curriculum status (C-19s attached ☐)

Anesthesia relationship, honestly: _____

JURISDICTIONAL BASELINE for this state: attached ☐ last reverified _____

ACCESS AND CREDENTIALS TO TRANSFER (systems, keys, portals)

OUTGOING SIGNATURE _____ DATE _____

INCOMING SIGNATURE _____ DATE _____

The paper version of 6.6’s indicator set: one sheet per quarter, filed in the facility’s QAPI records.

TOM PHARMACY CONSULTING, LLC · THE TOM PHARMACIST PROGRAM

Medication QAPI indicator table

Appendix C · Form C-33

FACILITY _____ QUARTER _____ PREPARED BY _____

INDICATOR THIS QTR PRIOR TREND DENOMINATOR

CS variance rate _____ ____ ____ per ____ entries

median days to closure _____ ____ ____

Temperature excursions _____ ____ ____ per ____ readings

share with corrective action _____ ____ ____

Expired / BUD stock found _____ ____ ____ per visit

Witnessed-waste completeness _____ ____ ____ per ____ wastes

Findings open past due _____ ____ ____ by severity: ____

Med errors / ADEs reported _____ ____ ____ per ____ cases

TWO SENTENCES PER INDICATOR (trend, and what is being done):

1 _____

2 _____

3 _____

4 _____

5 _____

6 _____

Presented to QAPI committee on _____ by _____

In TOM MMS this table assembles from the records the visits already verify; the two sentences per indicator remain the pharmacist’s part.

One project per year, documented from baseline to result, per 6.5's design rules and the federal documentation requirement in 42 CFR 416.43(d)(2): the reason for the project, and its results.

TOM PHARMACY CONSULTING, LLC · THE TOM PHARMACIST PROGRAM

Improvement project record

Appendix C · Form C-34

FACILITY _____ PROJECT YEAR _____

THE REASON (which indicator, and what number made it the pick)

BASELINE: measure _____ value _____ interval _____

WHAT NUMBER WOULD MEAN THE INTERVENTION WORKED (written before starting)

THE INTERVENTION (what changed in the system, not in the reminding)

REMEASURE: value _____ interval _____ same method as baseline ☐

THE RESULT, PLAINLY (including if nothing improved)

NEXT: keep ☐ adjust ☐ abandon and pick again ☐

Reviewed by QAPI committee _____ Medical director _____

For any medication event worth more than a log line: pairs with the investigation record (C-7) when controlled substances are involved, and holds 4.5’s line between correction, corrective action, and action item.

TOM PHARMACY CONSULTING, LLC · THE TOM PHARMACIST PROGRAM

Root cause and corrective action worksheet

Appendix C · Form C-35

FACILITY _____ DATE _____ EVENT NO. _____

WHAT HAPPENED (facts only, no adjectives)

_____

_____

THE CAUSE CHAIN (ask why until the answer is a system, not a person)

Why 1 _____

Why 2 _____

Why 3 _____

Root cause, stated as a system condition:

_____

IMMEDIATE CORRECTION (what was fixed on the spot) _____

CORRECTIVE ACTION (what changes so it cannot recur)

action _____ owner _____ due _____

verification: how we will know it worked _____

ACTION ITEM ONLY ☐ (a task, not a system change; say why that is enough) _____

PATTERN CHECK: has this happened before? no ☐ yes ☐ , when/where

_____

Individuals are not named on this sheet; patterns go up, people conversations stay in leadership's lane (Module 5).

Topic 10’s rule on paper: the answer to a surveyor is the record, retrieved. One sheet, posted inside the medication records binder.

TOM PHARMACY CONSULTING, LLC · THE TOM PHARMACIST PROGRAM

Survey evidence locator

Appendix C · Form C-36

FACILITY _____ LAST VERIFIED _____ BY _____

WHEN THE SURVEYOR ASKS FOR... THE RECORD IS... LIVES AT...

Controlled substance log C-5 sheets _____

Daily counts C-28 _____

Last reconciliation C-6 _____

Temperature and humidity logs C-11 _____

Excursions and corrective actions C-11 _____

Cart and seal checks C-12 / C-13 _____

Expired-stock control C-5 / C-26 _____

Staff training and competency C-18 / C-19 _____

Visit findings and closure C-3 / C-4 / C-15 _____

QAPI medication component C-33 / C-34 _____

Incident and RCA records C-27 / C-35 _____

Licenses and registrations C-30, posted at ___ _____

RETRIEVAL DRILL: pick three rows, time the pull ____ ____ ____

(under two minutes each is the standard; Topic 10)

The 6.4 leadership summary shaped for the packet: one page, no editing required before it goes to the board.

TOM PHARMACY CONSULTING, LLC · THE TOM PHARMACIST PROGRAM

Governing body medication report

Appendix C · Form C-37

FACILITY _____ PERIOD _____ PREPARED BY ____

THE STATE OF THE MEDICATION LAYER, ONE PARAGRAPH

INDICATORS (from C-33): attached ☐ headline number and its sentence

FINDINGS: open ____ closed this period ____ oldest open: age ___

status in one line _____

DECISIONS REQUESTED OF LEADERSHIP (with the cost of no)

1 _____

2 _____

WHAT IS COMING (next quarter's weather, per Module 8)

Reviewed by governing body on _____ Medical director _____

In TOM MMS the one-click compliance report carries this page’s data; the paragraph and the decisions requested remain judgment, which is the point of having a pharmacist.

One sheet per box per day. Topic 11 is the training; Phase 2h is the audit that reads this sheet.

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Anesthesia box issue and reconciliation record

Appendix C · Form C-38

FACILITY _____ DATE _____ BOX ID _____

PAR LIST version _____ contents verified against par at issue ☐

ISSUE: time _____ released from safe by _____

custody taken by (provider) _____

PER-CASE LINES

CASE NO. DRUG/STRENGTH	ISSUED	ADMIN	WASTED (witness) R	ETURNED

CASE-END RECONCILIATION (each case, two people, at the time)

case _____ provider _____ second counter _____

case _____ provider _____ second counter _____

mismatch found? ☐ No ☐ Yes -> secured, recounted, reported

(C-7 opened: _____)

RETURN: time _____ returned by _____ received into safe by

RESTOCK to par: by _____ verified by _____ time _____

SEALED-KIT VARIANT: kit seal out _____ seal in _____

exchanged whole ☐ reconciled at exchange ☐

Two signatures, same day, both balances moved. The hallway handoff’s replacement, per 2i.

TOM PHARMACY CONSULTING, LLC · THE TOM PHARMACIST PROGRAM

Inter-location transfer log

Appendix C · Form C-39

FACILITY _____ SHEET NO. ____

DATE/TIME	DRUG/STRENGTH	QTY	FROM location	SENT BY	TO location	RECEIVED BY

RULES ON THE SHEET: sender counts out, receiver counts in, both sign at the time of transfer; both location balances updated the same day; a transfer without a receiver signature is an open custody gap, reported per Topic 8.

For a pharmacist assessing their own practice against this standard, or a facility assessing its program. Annual, or at the start of an engagement. Honest answers only: this sheet has no audience but you.

TOM PHARMACY CONSULTING, LLC · THE TOM PHARMACIST PROGRAM

Program self-assessment

Appendix C · Form C-40

FACILITY _____ ASSESSED BY _____ DATE _____

THE NINE PROGRAMS OWNER CYCLE ARTIFACTS MEASURE RUNNING?

NAMED? KEPT? PRODUCED? REPORTED?

Controlled Substance ☐ ☐ ☐ ☐ Y / N / PART

Custody

Temperature Integrity ☐ ☐ ☐ ☐ Y / N / PART

Emergency Readiness ☐ ☐ ☐ ☐ Y / N / PART

Look-Alike and High-Alert ☐ ☐ ☐ ☐ Y / N / PART

Expiry and Returns ☐ ☐ ☐ ☐ Y / N / PART

Facility Team Competency ☐ ☐ ☐ ☐ Y / N / PART

Diversion Prevention ☐ ☐ ☐ ☐ Y / N / PART

Antimicrobial Stewardship ☐ ☐ ☐ ☐ Y / N / PART

Medication Quality ☐ ☐ ☐ ☐ Y / N / PART

THE ELEVEN COMPLETION CONDITIONS MET AT LAST VISIT?

Phase 1 arrival ☐ yes ☐ no ☐ n/a

Phase 2 controlled substances ☐ yes ☐ no ☐ n/a

anesthesia tray element ☐ yes ☐ no ☐ n/a

Phase 3 storage ☐ yes ☐ no ☐ n/a

Phase 4 emergency equipment ☐ yes ☐ no ☐ n/a

Phase 5 ordering and returns ☐ yes ☐ no ☐ n/a

Phase 6 compliance documentation ☐ yes ☐ no ☐ n/a

Phase 7 walkthrough ☐ yes ☐ no ☐ n/a

Phase 8 wrap-up and reporting ☐ yes ☐ no ☐ n/a

Freestanding emergency variant ☐ yes ☐ no ☐ n/a

Long-term care engagement stood up ☐ yes ☐ no ☐ n/a

FOUNDATIONS

Jurisdictional baseline written and dated ☐ yes ☐ no

A Lead is named, and a deputy is named ☐ yes ☐ no

Written agreement and BAA current ☐ yes ☐ no

Professional liability coverage current ☐ yes ☐ no

Records could be handed to a successor today ☐ yes ☐ no

THE THREE HONEST QUESTIONS

1. What did I record this year that I could not have shown a surveyor?

_____

2. Which finding have I raised more than twice without it closing, and what have I not tried? _____

3. If this facility had a diversion problem today, what would tell me?

PICK ONE THING TO FIX BEFORE THE NEXT ASSESSMENT

In TOM MMS most of the left-hand column answers itself from the records. The three honest questions do not, and they are the reason this sheet is worth the twenty minutes.

APPENDIX D

Training Handouts

APPENDIX D · TRAINING HANDOUTS

What this appendix is for. The teaching material from Parts 2 and 3, printed as instruments a person can hold: check scripts, session plans, drills, model answers, and one-sheet records. A handout states the standard’s own rules and defers to the jurisdictional baseline and facility policy wherever a state could differ. A handout is not a citation.

D.0 What this appendix is

Twenty-four instruments in three sets. Nine handouts for the pharmacist, keyed to the modules in 2.3 and ordered to match them. Eleven for the Facility Pharmacy Lead, one per curriculum topic in 3.1 plus the escalation poster. And a facilitation set, D-21 through D-24, for whoever delivers and records the training.

A form is a record. A handout is a teaching aid. Appendix C is what the program writes down. This appendix is what the program teaches from, and where it gets posted. The forms live in the binder. The handouts live at the cabinet, in a pocket, or on the wall beside the work they describe, because the curriculum in Part 3 is taught at the point of use and the point of use has no bookshelf.

Each handout is one page. Print it, post it or hand it out, and teach from it where the work happens. The case instruments and the facilitation set, D-3, D-6, and D-21 through D-24, are the exceptions: they are worked in a session or kept as records rather than posted.

The footer convention. Every handout ends with one italic line on how TOM MMS carries the same control. The standard is published for anyone. The program is sold as software. The honest way to hold both is to say the software’s part out loud, once, at the bottom, in a line the handout works without.

Rules discipline. A handout states the standard’s own rules and defers to the facility’s policy and the jurisdictional baseline wherever a state could differ. A handout is not a citation, and it never outranks the policy on the shelf beside it.

D.1 The pharmacist set

Nine handouts, in module order.

APPENDIX D

The Handouts

Handout D-1 · The setting, on one page

Module 1 compressed to a card. Read it before the first visit and again after the first visit, because the second reading is the one that lands.

There is no dispensing. Nothing leaves labeled for home. The questions are storage, accountability, and administration, so retail instincts about prescriptions find nothing to grab.

There is no pharmacist on site. Every control a hospital gives a pharmacy department, this building gives a nurse with a key. Design every recommendation for the person who will actually run it.

Anesthesia is a parallel system. Draws, labels, administers, and wastes largely alone, often from a cart treated as personal. Highest controlled substance volume, thinnest record. Do not avoid the conversation.

Immediate-use is a boundary, not a suggestion. A facility that has drifted past it into compounding has a problem it does not know it has. Know where the line is.

Volume is high, inventory is small. Significant fentanyl moves through a cabinet that never holds much. That ratio makes diversion easier to do and easier to see, if anyone is looking.

The building empties. Nights, weekends, holidays, nobody home. Access control matters more than in a place that never closes.

Turnover is constant. The person who ran the routine last quarter may be gone, and the knowledge left in their head. Train deliberately or inherit habits.

The test of the card: for each line, say what you would substitute for the hospital control that is missing. If you can, Module 1 landed.

TOM MMS assumes exactly this setting: no pharmacy department, a nurse running the routine, a pharmacist who visits. This card is the why behind that shape. —

Handout D-2 · Jurisdictional baseline worksheet

The output of Module 2, and the document a consultant returns to most often pharmacist owns. Complete it in writing, with a citation and a check date beside every answer, before the first visit in a state. Refresh it annually and after every legislative session.

```
JURISDICTIONAL BASELINE
STATE _____________   PHARMACIST _____________________
ESTABLISHED _________   LAST FULL REVERIFICATION _________

For each: ANSWER · SOURCE (citation) · AUTHORITY RANK · DATE CHECKED
Authority ranks: 1 statute · 2 board rule · 3 board guidance ·
4 written board answer · 5 context only, never authority

 1. ASC licensure: separate license? Under what chapter?
    A: ____________________  S: ___________  R: __  D: _______
 2. Which agency surveys, against what standards?
    A: ____________________  S: ___________  R: __  D: _______
 3. Consultant pharmacist required? Frequency? Deliverable?
    A: ____________________  S: ___________  R: __  D: _______
 4. PIC or equivalent designation? Posted?
    A: ____________________  S: ___________  R: __  D: _______
 5. State CS registration? Sequence vs DEA?
    A: ____________________  S: ___________  R: __  D: _______
 6. Reconciliation or periodic inventory beyond the federal biennial?
    A: ____________________  S: ___________  R: __  D: _______
 7. Storage and security beyond 21 CFR 1301?
    A: ____________________  S: ___________  R: __  D: _______
 8. Who may hold keys or access credentials, by license type?
    A: ____________________  S: ___________  R: __  D: _______
 9. Waste, returns, destruction. Witness requirements by license?
    A: ____________________  S: ___________  R: __  D: _______
10. Preparation and beyond-use dating rules for this facility type?
    A: ____________________  S: ___________  R: __  D: _______
11. Loss or discrepancy: what is reported to the board, on what
    timeline?
    A: ____________________  S: ___________  R: __  D: _______
12. Required medication policies, and their review cycle?
    A: ____________________  S: ___________  R: __  D: _______
13. Training or competency requirements for staff who handle
    medications?
    A: ____________________  S: ___________  R: __  D: _______
14. Privacy law stricter than HIPAA touching this work?
    A: ____________________  S: ___________  R: __  D: _______
15. Dispensing or supplying take-home medications, including a limited
    post-operative supply: permitted? Authority, limits, labeling?
    A: ____________________  S: ___________  R: __  D: _______
16. What changed in the last legislative session?
    A: ____________________  S: ___________  R: __  D: _______

THE TWO RESOLUTION RULES
Where more than one authority speaks, the strictest governs.
Where the state is silent, silence is not permission. Document the
judgment; where stakes warrant, put the question to the board in
writing.

KEEPING IT CURRENT
Board newsletter subscribed _________  Session end calendared _________
Next full reverification due _________
```

The baseline is pharmacist work no system does for you. TOM MMS holds you to the cadence and the records; which rules govern them is established here. —

Handout D-3 · Severity calibration case set

Ten short cases for Module 3. Read the observation, assign a severity, then compare against the calibration notes. The disagreements are the module. Work them in a group where possible, because calibration is visible only in comparison.

Case 1. The verification queue holds sixty entries, fifteen past the facility's window. The schedule allows time to work about twenty-five properly.

Calibration. Work them in risk order, verify only what you actually review, and document the remainder as a backlog finding, Important, with the coverage cause named if you can find it. The trap is the queue itself: clearing it mechanically to zero converts an honest backlog into a false record with your name on it.

Case 2. The perpetual inventory balances to the shelf. The month's entries are in one handwriting, one ink, visibly one sitting.

Calibration. Important, regardless of the arithmetic. The record is reconstructed, not contemporaneous, and a reconstructed record proves nothing about the month it claims to describe. The trap is the correct balance.

Case 3. The refrigerator log shows three out-of-range readings this month. The corrective action column is blank all three times.

Calibration. Important, and the blank column is the finding rather than the excursions. A facility that notices and does nothing is worse than a facility with a warm afternoon. The trap is writing the finding about the temperatures.

Case 4. During turnover you see an unlabeled syringe on the prep counter. A nurse says it is hers, propofol, going in within the minute.

Calibration. Critical, raised now, in the room. The explanation is entirely plausible and changes nothing: an unlabeled syringe is unidentifiable the moment she turns her back. The trap is the reasonable explanation.

Case 5. The MH cart stocks the concentrated dantrolene formulation, three vials, in date. Facility policy still requires thirty-six vials of the conventional product.

Calibration. Important. Clinically the cart is fine; on paper the facility fails an audit against its own policy. Fix the policy, not the cart. The traps are two: inflating this to Critical, and fixing the wrong side of the gap.

Case 6. A destruction record has been open ninety-four days. The quarantined quantities match the record exactly.

Calibration. Important, trending Critical with age. Everything is accounted for today; the aging itself is the exposure, and the obvious investigator question is what happened to the drug in the meantime. The trap is the matching count.

Case 7. The incident log shows zero entries in eleven months at a three-OR center.

Calibration. Important, written as a reporting-culture finding rather than a safety achievement. Facilities this size have incidents; this one has stopped writing them down. The trap is that it looks like good news.

Case 8. A med cabinet latch is taped over. A nurse explains the badge reader takes three tries with gloves

on, and the first case starts at 0700.

Calibration. Important, and write the workaround with its cause, not just the violation. The tape is the symptom; the badge reader is the finding. The trap is citing the tape and leaving the reason it exists.

Case 9. Over six weeks, one nurse’s waste entries carry the same witness eighty-four percent of the time. Everything is signed, quantities normal.

Calibration. Document the pattern factually and route it to the diversion review process. Severity is honestly uncertain: rank it Important and say in the finding why you were uncertain, which a reviewer can downgrade. Pattern, never person, and no diagnostic language in a routine record. The trap is writing a conclusion about an individual you have not investigated, in a document that will be read aloud someday.

Case 10. The DEA registration expires in seventy days. The person who filed the original left last year. Nobody has started the renewal.

Calibration. Informational today, with a date on it, and it becomes Critical by itself if nothing happens. Name an owner now, because a lapsed registration stops the facility. The trap is filing a coming deadline as merely informational and then not tracking it.

In TOM MMS a finding cannot be saved without a severity, an owner, and a date. The fields enforce the discipline; this case set is where the judgment behind the severity field gets calibrated. —

Handout D-4 · The visit pocket card

The eight phases, their completion conditions, and the close. Carry it until Module 3 makes it unnecessary, then carry it anyway.

```
1 ARRIVE          Summary read. Postings verified and dated.
                  Leadership asked: what changed, what worries you,
                  what should I look at.
2 CONTROLLED      Queue worked or backlog documented. Blind count
  SUBSTANCES      recorded. Reconciliation saved. Every variance
                  documented before investigation. Access examined,
                  not assumed.
3 STORAGE         Every named location, six questions. Refrigeration
                  incl. excursion handling. Beyond-use as a practice,
                  not a snapshot.
4 EMERGENCY       Carts and boxes vs current lists. Seals and logs
                  for the full interval. Last drill asked about.
5 ORDERING &      222/CSOS in sequence. Receiving reconciles.
  RETURNS         Nothing aging in the destruction path.
6 DOCUMENTATION   Incidents closed or owned. Training current per
                  person. Manual vs practice. Audit trail examined.
7 WALKTHROUGH     Arrival > storage > preparation > administration >
                  waste. Watch someone do something. Write down the
                  workarounds.
8 WRAP-UP         Debrief in person, good news first. Owners and
                  dates agreed out loud. Next visit scheduled.

THE CLOSE, before signing:
[ ] Every phase complete, N/A, or issue found. None pending.
[ ] Every issue has an action item or CAPA, owned and dated.
[ ] Reconciliation saved; variances documented and in
    investigation.
[ ] Excursions and check gaps have corrective actions.
[ ] Education log records any session, with attendees.
[ ] Narrative summary attached, 2 to 5 sentences.
[ ] Signed, real signature, real time. Submit within 24 hours.

Skipped and recorded is a working program.
Skipped and marked complete is the one unforgivable thing.
```

TOM MMS runs these phases as the visit checklist and flags an incomplete visit before it is marked complete. The card is for knowing them without looking.

Handout D-5 · Writing the finding: five pairs

Module 4’s companion. Each pair is the same observation twice. The weak version is true and useless. The strong version is dated, sourced, owned, and falsifiable, which is what makes it actionable.

Pair 1 · Phase 2

Weak: “Verification backlog exists.”

Strong: “Fourteen Schedule II entries recorded 3 to 9 August are past the facility’s 72-hour verification window as of this visit, per facility policy 5.2. Eleven of the fourteen were recorded by float staff during the Pharmacy Lead’s leave week, which makes the gap a coverage problem rather than an entry problem. Owner: DON. Due: backlog cleared and a trained deputy named before the next visit.”

Pair 2 · Phase 3

Weak: “Fridge issues.”

Strong: “The main drug room refrigerator log records in Fahrenheit; facility policy MM-07 states the acceptable range in Celsius. Every August reading falls inside both ranges, so nothing was harmed, and nothing protects the next reading from being judged against the wrong scale. Owner: Pharmacy Lead. Due: log and policy in one unit within two weeks.”

Pair 3 · Phase 4

Weak: “Crash cart log incomplete.”

Strong: “The crash cart check log records the same seal number for nineteen consecutive days, including 22 July, when the education log shows the cart opened for a mock code. A seal recorded intact after a documented opening is a carried-forward number, not an observation. Owner: Pharmacy Lead. Due: full internal check, reseal, and the check re-taught this week.”

Pair 4 · Phase 5

Weak: “222 forms disorganized.”

Strong: “The DEA Form 222 sequence on file runs 041 through 057 with 049 absent and not recorded as voided. A missing form number is a finding on its own under the Part 1305 recordkeeping rules, independent of whether an order was ever placed on it. Owner: Administrator. Due: locate 049 or document its disposition within seven days, with a written question to the supplier if not found.”

Pair 5 · Phase 6

Weak: “New staff need training.”

Strong: “Three nurses hired since the June visit have administered medications; a competency record exists for one. Facility policy HR-11 requires training before medication handling, and 42 CFR 416.48 places administration under accepted professional practice. Owner: DON. Due: the two missing records completed as demonstrated competency, per person, before the next visit, with interim supervision documented.”

What changed, all five times: a date, a source, an owner, a due date, and a sentence that could be

proven wrong. The weak versions cannot be acted on or falsified. The strong versions can be both.

In TOM MMS the finding record carries the same five elements as Form C-3. The software supplies the structure. These pairs teach the writing that goes in it. —

Handout D-6 · One variance, eight steps

Module 5’s worked example. A discrepancy investigation run once, on paper, so the sequence is familiar before it is ever needed.

The observation. Tuesday reconciliation. Fentanyl 100 mcg/2 mL: expected 46, counted 46 twice, blind. Expected balance per the perpetual inventory: 48. Variance: short 2.

Step 1 · Document before anyone explains. The C-7 opens now: drug, strength, expected 48, counted 46, variance 2, found 0910 Tuesday. Nothing else is written yet because nothing else is known yet.

Step 2 · Preserve. The log sheet is photographed and set aside. Nobody corrects anything, including the helpful person reaching for a pen.

Step 3 · The window. Last clean reconciliation was the prior Tuesday. Seven days.

Step 4 · Access. Eleven people held access during the window: eight staff nurses, two anesthesia professionals, one float covering Wednesday and Thursday.

Step 5 · Interview, without accusing. Open questions, in order of who touched the log most. The float nurse, asked to walk through her Thursday entries, says she recorded two witnessed wastes and points to them. They are on the fentanyl 50 mcg sheet. She was covering an unfamiliar cart and the log sheets are ordered differently from her home facility.

Step 6 · Corroborate, then determine cause. The 50 mcg sheet shows a mirrored variance: over by 2. Two witnessed waste entries, right day, right witness, wrong sheet. Mirrored variances across adjacent strengths are the classic signature of a documentation error, and here the witness confirms the waste happened as recorded. Cause: documentation error.

It is still two findings. The count was wrong and the record was wrong, and the amendment fixes only the record. The wrong-sheet entries are amended per the amendment rule, originals preserved, corrections co-signed. And because the cause is a log layout that fails visiting staff, a CAPA opens: the sheets get labeled and ordered the same way at every cart, and the float orientation gains a two-minute log walkthrough.

Step 7 · The reporting analysis, every time. Loss was not established; the drug is accounted for. The C-7 records the analysis anyway: the federal significant-loss standard considered, the state baseline question 11 answer cited, conclusion “report not required,” dated and signed. An analysis that concludes no report is still an analysis, and it is the part an investigator reads first.

Step 8 · Verify the fix took. Next visit: relabeled sheets confirmed at every cart, float orientation checklist updated, no wrong-sheet entries in the interval. The CAPA’s effectiveness check passes and closes.

Where this stops being yours. If Step 5 had produced no explanation, or the entries had pointed at a person rather than a layout, the investigation passes to facility leadership and counsel at that moment. The pharmacist documents, hands over, and stays available. A consultant who keeps interviewing past that line has become an employment investigator without the role or the protection.

In TOM MMS the variance is documented the moment the reconciliation saves, before any explanation

exists. The sequence on this page is the reason the software works in that order. —

Handout D-7 · The refusal card

Module 7’s card. Five asks you will hear, usually from decent people under real pressure. Decide the answers now, because inventing them in the moment is how people say yes. Every refusal carries its path forward, because a no with a path forward is accepted and a bare no is resented.

“Can you date it Friday? That’s when we actually did it.”

I cannot record it that way. I can record it today with a note that the work happened Friday, which is the version that protects you if anyone ever asks.

“Can you soften the wording? The owner reads these.”

I cannot change what it says happened. I can add what is already being done about it, and that reads better because it is better.

“Leave the fridge thing out. We’re fixing it tomorrow.”

I cannot leave it out. I can record it with tomorrow’s fix and a date, and next visit it closes with evidence, which is the strongest thing this report can say about you.

“You don’t need to open every one. Just verify the queue, we’re slammed.”

I cannot sign records I did not review. I can verify what I can do properly today and record the rest as a backlog with a plan. A backlog honestly reported is a functioning program.

“Just sign the visit complete. You can finish the walkthrough next week.”

I cannot sign it complete. I can sign it with the walkthrough recorded as deferred to next week, which is normal, honest, and keeps the record true.

The stance behind all five: the record says what actually happened. That sentence is the whole program, and it is the one thing with no flexibility in it.

TOM MMS makes several of these asks structurally impossible: a saved controlled-substance record and a submitted visit record cannot be altered, a correction is made as an amendment that preserves the original, and each entry carries who recorded it and when. The sentences are for everything the software cannot refuse for you. —

Handout D-8 · The five numbers

Module 8’s card. The drug line is a real cost that almost nobody in the building can read. You can. These are the five numbers an administrator actually wants, each with its denominator and the sentence that delivers it.

```
1  DRUG SPEND PER CASE, trailing, with the case count beside it.
   The sentence: "Spend per case is X this quarter against Y last,
   on Z cases."

2  WASTE AS A SHARE OF SPEND, and what drove it.
   The sentence: "N percent of spend was wasted, and most of it is
   one drug and one habit, both fixable."

3  THE TOP MOVERS: the three drugs whose cost changed most, and why.
   The sentence: "Three items explain most of the change: price,
   volume, or a switch. Here is which."

4  PAR AGAINST USE: what is stocked against what is actually used.
   The sentence: "We hold A days of B and use it in C. That is
   cash on a shelf."

5  WHAT IS COMING: a renewal, a formulation change, a shortage on
   this formulary.
   The sentence: "This is not a problem today. It is a decision
   with a date on it."
```

The three rules of saying it. Dollars, not doses. Never a number without its denominator. Never a surprise in writing: a number that will land badly is raised in person first, exactly like a finding.

And always both halves. The spend conversation earns attention for the compliance conversation, and a pharmacist who brings only one becomes only that. Section 5.2’s rule, on a card.

In TOM MMS the spend and usage behind these numbers assemble from the records the facility already keeps. The sentences are yours.

Handout D-9 · The forward look

Module 9’s card. A reactive consultant reports what happened. A proactive one changes what happens next. Bring three forward items to every debrief, each with a date, a source, and an owner, or it is noise.

```
THE STANDING SCAN, against THIS facility's formulary and calendar:

[ ] Expirations inside 90 days (C-30): licenses, DEA, CSOS
    certificate, accreditation                  date ____ owner ____
[ ] Survey window and accreditor standards version
    (the v44 lesson in 6.5)                     date ____ owner ____
[ ] Federal biennial inventory due date         date ____ owner ____
[ ] Board newsletter read; legislative session
    end calendared (A.4)                        date ____ owner ____
[ ] FDA shortage and recall feeds checked against
    the formulary, not the news                 date ____ owner ____
[ ] MHAUS guidance vs the cart actually stocked
    (the dantrolene lesson in 4b)               date ____ owner ____
[ ] Contract and GPO renewals approaching       date ____ owner ____
[ ] Staff turnover since last visit: who needs
    training before it becomes a finding        date ____ owner ____

THREE ITEMS FOR THIS DEBRIEF:
1 _____________________________________________ date ____ owner ____
2 _____________________________________________ date ____ owner ____
3 _____________________________________________ date ____ owner ____
```

Anticipatory findings are the cheapest work in the program. Writing tomorrow’s Critical as today’s Informational with a date and an owner is the whole trick, and case 10 in Handout D-3 is the worked example.

What proactive is not: alarmism, hedging every possibility, or manufacturing urgency. A forward item without a date and an owner is a worry, and worries do not go in the record.

In TOM MMS the compliance calendar carries the dated items. The scan against your formulary, and the three items you bring, are the pharmacist’s part.

D.2 The Pharmacy Lead set

Eleven one-pagers, one per curriculum topic plus the escalation poster. Post each where the work it describes happens. Teach at the cabinet, hand the card over, and leave it there.

Handout D-10 · The five entries

An incomplete entry is not a paperwork gap. It is an unaccounted quantity of a controlled drug. Five entry types, and what each one proves.

ENTRY	WHEN	WHAT IT PROVES
SIGN-OUT	Drug leaves storage	Who took custody, for whom, on whose order
ADMINISTRATION	Drug given	The dose reached the patient it was signed out for
WASTE	Unused portion destroyed	The remainder went nowhere, and a witness saw it go
RETURN	Unopened drug back to storage	Custody came back intact
TRANSFER	Custody changes hands	The chain has no gap in it

Every entry carries: patient identifier, drug, strength, quantity, location, ordering practitioner, date and time, and you. A field you cannot complete is completed as N/A, never left blank, because a blank is indistinguishable from a skip.

At the time of the event. Entries batched at the end of a shift are a reconstruction, and a reconstruction proves nothing about the shift.

The chain test: for any vial, the entries should answer where it came from, where it went, and who watched. If any answer is missing, the entry type that would have supplied it was skipped.

In TOM MMS these same five entries structure the controlled substance record. The card is what each field is for, so the entry is made rather than filled. —

Handout D-11 · What a witness is

Your credential says: I personally watched this happen.

Not “I trust her.” Not “I was nearby.” Not “she asked me to.” A witness signature attests that you, yourself, saw the drug wasted, at the moment it was wasted.

The three rules

1. Your credential never leaves your hands. Not your PIN, not your badge, not your login. Not for anyone, not for a minute.
2. You witness at the moment. A waste witnessed later is a story, not a witness.
3. You sign only for what you actually saw. If you looked away, say so and start over.

The sentence, for when someone senior is in a hurry:

“I can’t enter my credential for you. I’ll come witness it right now.”

Offering to come now is the whole answer. It solves their problem and keeps the record true.

Why this protects your colleague. Shared credentials are the pattern that makes diversion invisible. A colleague with a substance problem is a clinician in trouble, and invisibility is the thing that keeps them in it. Witnessing properly is not suspicion. It is the protection working.

Seniority does not change what a witness is.

In TOM MMS a witness authenticates in their own credential at the moment of waste. This card is why that is the whole point. —

Handout D-12 · Temperature out of range

Post on the unit. Six steps, in order.

1. **Record the reading.** The real number, now. Never round it into range.
2. **Note the duration if known.** When was it last in range?
3. **Quarantine the affected stock.** Set apart, marked, not used.
4. **Notify.** The Pharmacy Lead now. The pharmacist same day if any temperature-sensitive drug is involved.
5. **Document the corrective action.** What was done, by whom, when. In the log, next to the reading.
6. **The pharmacist decides usability.** Not nursing, not the fridge feeling cold again. Nothing leaves quarantine without that determination.

The blank column rule. An excursion with a corrective action is a working program. An excursion with a blank corrective action is a facility that noticed a problem and did nothing, and that is the worse finding.

You are not in trouble for a warm afternoon. The building is judged on what happened next.

In TOM MMS the corrective action is recorded beside the reading, and a blank shows as a gap. These six steps are what belongs in it. —

Handout D-13 · The seal is broken

A seal is a claim: nothing inside has changed since the last full check.

A broken, missing, or mismatched seal means that claim is gone, and the cart is unverified until someone verifies it.

Five steps

1. **Stop.** Do not reseal, do not tidy, do not carry on with the check.
2. **Record it.** Old seal number, condition found, date, time, your name.
3. **Full internal check.** Every item against the current contents list. Not a glance. The list.
4. **Restock and document** anything missing, expired, or used.
5. **New seal, new number, recorded.** Lead notified, pharmacist notified.

Never copy yesterday's number. A seal number written down without being looked at is a false claim about emergency equipment, and it is the kind an auditor finds in one pass.

A broken seal with a documented check is a normal day. A broken seal with a carried-forward number is a finding.

In TOM MMS every check records the seal number fresh, so a carried-forward number has nowhere to hide. This card is what to do when the number is wrong. —

Handout D-14 · Vials and dates, quick reference

Two different dates, and they are not interchangeable.

Manufacturer expiration: on the label, applies to the unopened container.

Beyond-use date (BUD): the clock that starts when a container is opened, entered, or a dose is drawn. It is almost always sooner than the label date.

The four rules

1. **Multi-dose vial:** dated when first entered. Discarded at the BUD in facility policy, even if the label date is months away.
2. **Single-dose vial:** one patient, one use, never retained. This is the most commonly broken rule in the building and the one with real infection-control consequence.
3. **Anything drawn in advance:** labeled with drug, strength, BUD time, and who drew it. Discarded at the time.
4. **An opened, undated vial is discarded.** Not estimated, not given the benefit of the doubt. Undated means unknown, and unknown loses.

The policy states the number. You state the policy. If you cannot, tell the Lead, and the Lead asks the pharmacist. Knowing where the answer lives counts as knowing.

In TOM MMS beyond-use dates live on the record. This card is the rule that decides what gets written there. —

Handout D-15 · Label it: drug, strength, time, you

Four things, on everything, every time.

```
DRUG        what is in it
STRENGTH    how much per mL
TIME        when it expires or must be discarded
YOU         who drew it
```

Including the one you will use in ninety seconds. The ninety-second syringe is the dangerous one, because the person who draws is not always the person who gives, and the moment your back turns, an unlabeled syringe is an unidentifiable syringe.

On a sterile field, same rule. An unlabeled syringe on a sterile field is a finding every accreditor cites, and it is cited because it has hurt people.

Found unlabeled? It is discarded. Not sniffed, not remembered, not vouched for. Nobody can identify a clear liquid by confidence.

The habit that makes it stick: the label goes on before your hands move to the next task. Label, then move. Every time, until it is not a decision anymore.

TOM MMS cannot see a syringe. The label is the one control that is entirely in your hands, which is why this card is on the wall. —

Handout D-16 · Noticing, and who to tell

This card protects your colleagues. Read it that way.

A nurse or provider with a substance problem is a clinician in trouble. A building where nobody notices leaves them in trouble until something irreversible happens, to them or to a patient. Noticing is not an accusation. It is the first protective act.

Worth noticing

- Waste consistently unwitnessed, or always the same witness
- Quantities that do not fit the case
- One person recording far more waste than their peers
- Discrepancies that cluster around one shift, person, or location
- Records completed late, in batches, after the fact
- Sign-outs with no matching administration or waste
- Volunteering for the drug keys, every time

What to do: tell the pharmacist and the DON what you observed. Facts and dates, not theories. The facility’s process keeps it confidential.

Uncertainty is enough. You do not have to be sure. You are not deciding anything. You are handing a pattern to the people whose job it is to look.

What not to do: do not confront the colleague, do not investigate, do not watch and wait for more proof, and do not discuss it at the station. Each of those feels reasonable and each one makes it worse.

In TOM MMS these patterns are visible across weeks of records instead of one shift’s memory. Saying what you noticed is still a human act, and it is yours. —

Handout D-17 · The count doesn’t match

Post where the count happens. Three things, in this order, nothing else.

1. **Do not alter anything.** Not the log, not the count, not even to help. Not even if you can see exactly what went wrong.
2. **Write down what you observed.** What you counted, what the record says, when, exactly as found.
3. **Notify the pharmacist and the PIC. Now.** Not at the end of the shift. Not after checking with a colleague first.

The instinct to fix the count is the most damaging thing possible here. A corrected record destroys the evidence of what happened and makes an honest error look like concealment. The record as found is what protects you.

You are not in trouble for finding it. A discrepancy found and escalated is the system working. Unsure whether it even counts as a discrepancy? Unsure is enough. Escalate.

In TOM MMS the count and the record meet in the pharmacist’s reconciliation. Your part is these three steps, in order. —

Handout D-18 · The pharmacist is coming Thursday

The visit goes twice as far when the records are waiting instead of being found. Pull this list the day before.

```
[ ] Controlled substance logs since the last visit, and the
    verification queue status
[ ] Temperature logs, all units, with corrective actions visible
[ ] Cart and box check logs, and any seal events (C-13s)
[ ] Open findings, with the evidence you have gathered for the
    ones you own
[ ] Incidents since the last visit, with what was done
[ ] New hires since the last visit, and their training status
[ ] Anything expiring inside ninety days
[ ] Keys and access for the areas the visit will enter

[ ] YOUR OWN LIST: the things that bothered you since last time.
    A drawer that sticks. A workaround someone invented. A question
    nobody could answer. This is the most valuable item here.
```

Bring your list to the debrief unprompted. The pharmacist asks leadership what changed and what worries them. You are the person who actually knows. The program works best when you arrive with the answer before the question.

In TOM MMS the since-last-visit summary assembles most of this list by itself. The last item is the one it cannot. —

Handout D-19 · When the surveyor asks you

Six questions surveyors actually ask, with the shape of a good answer. Fill in your facility’s specifics and practise out loud.

“Where is your malignant hyperthermia cart?” “In [location]. The dantrolene and the MHAUS poster are inside, and the check log is on the cart. Last check was [date].”

“What do you do with an expired medication?” “Remove it, quarantine it in [location], and log it. It goes out through the destruction process, not the trash.”

“How do you report a medication error?” “Through [system/form]. The physician is notified, it goes in the record, and it is reviewed. Reporting is expected here, including near misses.”

“Show me your temperature log for last month.” “It’s right here. [Retrieve it.] Out-of-range readings have the corrective action written next to them.”

“Who is your consultant pharmacist, and when were they last here?” “[Name]. Last visit was [date], and the visit record is available. They’re reachable between visits.”

“What happens if a count doesn’t match?” “Nothing gets altered. I document what I found and notify the pharmacist and the PIC immediately. There’s an investigation process from there.”

The three rules of answering: short, true, and then stop talking. Nobody expects you to quote a regulation. “I don’t know, but I know exactly where it’s written” is a passing answer. A guess is the only failing one.

In TOM MMS the log, the visit record, and the last sign-off are retrievable while the surveyor is still standing there. The answers on this card are for saying so calmly. —

Handout D-20 · Who to call, posted

Print, fill in the names, post where the Lead works. Everyone should be able to answer “who do I call” without thinking.

PHARMACIST _____ DIRECT LINE _____
PIC _____ DON _____

SITUATION	WHO ACTS FIRST	WHO IS TOLD, WHEN
Controlled substance discrepancy, any size	Lead documents, does not alter	Pharmacist + PIC, immediately
Suspected diversion	Lead documents observation only	Pharmacist + DON, immediately. Not the colleague.
Temperature excursion	Lead executes corrective action	Pharmacist same day if temp-sensitive drug affected
Expired stock in an active location	Lead removes and quarantines	Pharmacist at next contact; immediately if administered
Medication error or adverse reaction	Facility process; physician notified	Pharmacist same day
Survey or inspector arrives	Administrator	Pharmacist immediately
Lead is unsure	Lead escalates	Pharmacist. Uncertainty is sufficient reason.

Unsure is a valid reason to escalate. Nobody is in trouble for asking. The only costly answer is the one nobody raised.

In TOM MMS the escalation reaches the pharmacist inside the system and is recorded when it does. The poster exists because the wall works even when nobody is near a screen. —

D.3 The facilitation set

Four instruments for whoever delivers and records the training. The handouts above are for the learner. These are for the teacher, and they exist so the curriculum can be run by a pharmacist who did not write it. D-21 and D-22 make the Lead curriculum deliverable. D-23 makes Module 7 practicable. D-24 keeps the pharmacist’s own record, and it lives here rather than in Appendix C so that forty paper forms stays true.

Handout D-21 · Competency check scripts, Topics 1 to 11

The assessor’s side of Form C-19. Each check is observed one to one, at the point of use, doing rather than describing. Record the result on C-19 the same day, with the date and the assessor. A near pass is retaught and reassessed on a named date, never waved through, because a waved-through competency is an attendance record wearing the wrong title.

Topic 1 · CS logging. Stage: a blank perpetual sheet and five scenario slips, one per entry type. Ask: “Record these five events as they happened.” Pass: all five entry types recorded with every field completed or marked N/A, balances correct, entries made as they go rather than batched at the end. Common fail: the witness field left for later. Reteach the contemporaneity rule, not the arithmetic.

Topic 2 · Witnessing. Stage: a colleague, briefed, says “I’m slammed, just punch in your PIN for my waste.” Pass: refuses the credential handover and offers to come witness now, and can say in their own words what a witness signature attests. Common fail: the refusal without the offer. The offer is the answer.

Topic 3 · Temperature. Stage: a log with one out-of-range reading planted. Ask: “Run this morning’s check.” Pass: records the real value, catches the excursion, and executes the six steps unprompted, including quarantine, notification, and a written corrective action, and states that the pharmacist decides usability. Common fail: corrective action described out loud but never written. The column is the point.

Topic 4 · Cart and box checks. Stage: the log’s last seal number does not match the seal on the cart. Pass: notices without being told, stops, and states the sequence: record it, full internal check against the list, then reseal with a new recorded number. Common fail: reads the number off the log instead of off the seal. That is the exact habit the check exists to break.

Topic 5 · Expired and beyond-use dating. Stage: one expired vial and one opened, undated multi-dose vial planted in a storage area. Ask: “Walk this cabinet.” Pass: finds both, states the multi-dose vial rule from memory, and discards the undated vial rather than estimating a date for it. Common fail: the front row checked, the back row trusted.

Topic 6 · Labeling. Stage: ask them to prepare a syringe while you call out time pressure. Pass: drug, strength, beyond-use time, and preparer on the label before it leaves their hand, and they can say why the using-it-in-a-minute exception is the dangerous one. Common fail: labeled after drawing the second item. The label goes on before the hands move on.

Topic 7 · Diversion awareness. No staging. Ask: “Name four red flags. Now: you notice one of them about a colleague you like. What exactly do you do?” Pass: four flags, then tells the pharmacist and DON the facts and dates, does not confront, investigate, or discuss at the station, and says some version of “I don’t have to be sure.” Common fail: “I’d keep an eye on it.” Watching and waiting is the named wrong answer.

Topic 8 · Discrepancy response. Stage: a count that will not match the record. Say: “You count 44. The record says 46. Go.” Pass: alters nothing, writes down what was observed, and notifies the pharmacist and PIC immediately, in that order. Common fail: recounting five times before telling anyone. Two careful counts, then the call.

Topic 9 · Working with the pharmacist. Ask: “The pharmacist is here Thursday. Show me what you get ready.” Pass: produces the pull list without prompting and includes their own list of things to raise. The

own-list is the pass condition. Common fail: perfect logistics, nothing to raise.

Topic 10 · Survey readiness. Ask the six questions from Handout D-19, cold, out loud. Pass: six short, accurate answers with no guessing, where “it’s in the log, let me show you” counts as a full answer. Common fail: the confident guess. One guess fails the check; retrain the stop-talking rule.

Topic 11 · The anesthesia box. Stage a box one unit short and say: “Run the case-end reconciliation with me.” Pass: counts line by line out loud, catches the short, secures before searching, and names why the second counter exists. Common fail: hunting for the missing unit before securing the box; one hunt fails the check.

In TOM MMS competency currency is a query rather than a search through a folder. These checks are what put a true answer behind the query. —

Handout D-22 · Session plans for the Lead curriculum

The eleven topics of 3.1, delivered as three cabinet-side sessions plus a new-hire path. Teach where the work happens, four learners at most, and end every session with C-19 entries or a named reteach date. The deputy attends everything.

Session A · The log and the line (about 70 minutes, at the CS cabinet) Topics 1, 2, 8, and 11. Bring: a blank C-5, the scenario slips, Handouts D-11 and D-17, and blank C-19s.

Ten minutes on why the log exists: an incomplete entry is an unaccounted quantity of a controlled drug, not a paperwork gap. Twenty minutes hands-on: every learner records all five entry types. Ten minutes on witnessing, with the refusal sentence said out loud by each person, because a sentence never spoken is not owned. Ten minutes at a staged anesthesia box: two learners run Topic 11’s reconciliation out loud and hit the planted short. Ten minutes on the discrepancy drill: stage the mismatch, watch the three steps. Ten minutes to run the Topic 1, 2, and 8 checks from D-21 and sign C-19 where demonstrated.

Session B · Cold chain and the clock (about 50 minutes, at the refrigerator and med room) Topics 3, 5, and 6. Bring: the unit’s C-11, planted expired stock, Handouts D-12 and D-14, labels and pens.

Run a live temperature check, then walk the six excursion steps against the planted reading. Teach the two dates, then hunt the cabinet: the plants are the exam. Finish with labeling under called-out time pressure. Check and sign per D-21.

Session C · Seals, signals, and surveyors (about 50 minutes, at the carts) Topics 4, 7, 9, and 10. Bring: C-12, C-13, Handouts D-13, D-16, D-19, and D-20.

Run a live cart check with the seal mismatch staged. Walk the broken-seal steps. Then slow down for diversion awareness: ten unhurried minutes, framed exactly as D-16 frames it, protective and serious, because this topic taught badly is worse than not taught. Close with visit preparation and the six survey questions as rapid fire. Check and sign per D-21.

The new-hire path. Sessions A through C inside the first two weeks, and before unsupervised medication handling if facility policy requires training first, which it should. Compress the schedule, never the demonstrations. A new hire who attended but never demonstrated has inherited habits with a certificate on top.

Scheduling reality. These fit between cases, and they will get interrupted. Split any session at a natural seam rather than rushing a demonstration, and record the half that happened on C-18 so the record says what actually occurred.

In TOM MMS each session lands in the education log with attendance the day it runs, and the demonstrated competencies land per person. The plan on this page is the part the software cannot deliver for you. —

Handout D-23 · Role-play scripts for Module 7

Three scenarios. Each runs five minutes of scene and five of debrief, twice, with the pressure turned up the second time. The facilitator never breaks character to rescue the trainee, because the moment of nobody-helping is the module. The goal is sentences that survive pressure, not a performance.

Scenario 1 · Delivering the critical finding

Cast: trainee as pharmacist, facilitator as a DON having a genuinely bad day. Setup: the pharmacist has just observed an unlabeled syringe on the prep counter during turnover; the nurse said it was hers and going in within the minute.

Facilitator's pressure moves, in order: defend the nurse ("she's my best one, she'd never make an error"), minimize ("it was in her hand thirty seconds later"), and deflect to paper ("just put it in the report, I have a surveyor problem and two call-outs").

What good looks like: the observation stated factually, why it matters in one sentence, then the question: "what do you think happened there?" The question is the test. Then a next step agreed now, in the room. The trainee never says "violation" where "gap" is accurate, and never retreats to the report because the conversation got uncomfortable.

Debrief on: where it tipped toward accusation, and where it tipped toward mush. Both failures lose the DON, in different ways.

Scenario 2 · The backdate ask

Cast: facilitator as a likable administrator with a survey Friday. Setup: two entries from Monday's work were never signed, and the administrator asks the pharmacist to date them to last week, "when we actually did the work, it's just accurate."

Pressure moves: reasonableness first ("it's not lying, it's when it happened"), then stakes ("you'd sink us over a formality"), then the personal card ("I thought you were on our team").

What good looks like: the refusal sentence with its path forward attached, delivered warm and delivered once: "I cannot record it that way. I can record it today with a note that the work happened Monday, and that version protects you." Then holding, without re-arguing, while staying in the relationship.

Debrief on: the exact sentence used. Did the alternative arrive attached to the no, or did the no stand alone long enough to be resented?

Scenario 3 · The pattern conversation

Cast: facilitator as a DON. Setup: the trainee must raise the witness concentration pattern from case 9 of Handout D-3: one nurse's wastes carry the same witness 84 percent of the time over six weeks. Everything is signed. Quantities are normal.

Pressure moves: the direct question ("are you telling me she's stealing?"), then the push for a verdict ("well is it a problem or isn't it"), then loyalty ("I'm not putting my nurse through a review over a hunch").

What good looks like: pattern language, facts and dates, and an explicit sentence that this is not an accusation: "I'm not saying anything about anyone. I'm saying this pattern needs the process, and the

process exists to protect her too.” Then handing it to leadership and staying available. The trainee refuses the verdict question both times it is asked.

Debrief on: any diagnostic language that slipped out under the direct question. One slipped conclusion in the room becomes a quoted conclusion later.

TOM MMS holds the record steady while these conversations happen. The conversations are the part no software has, and they are practiced for the same reason the count is. —

Handout D-24 · Pharmacist training record

The record 2.4 requires, as one sheet per pharmacist. It sits in this appendix rather than Appendix C so the forty forms stay the facility's record set and this stays the pharmacist's own.

```
PHARMACIST TRAINING RECORD
NAME _____________________  LICENSE NO. _________  STATE ____
LICENSE EXPIRES _________  LAST VERIFIED _________ BY _________

PREREQUISITES (2.3)                              DATE      REF
1 License active, unencumbered, verified         _______   _______
2 Professional liability coverage                _______   _______
3 Agreement and confidentiality executed         _______   _______
4 BAA executed (per facility; list refs)         _______   _______
5 HIPAA workforce training                       _______   _______
  Retraining trigger noted: material legal change,
  no later than one year after (confirm your state)

MODULES (2.3)                    COMPLETED  TRAINER/   "LANDED" EVIDENCE
                                            METHOD     (the module's own test)
1 The ASC setting                _________  _________  _____________________
2 The regulatory spine           _________  _________  Baseline attached: [ ]
3 The visit standard             _________  _________  _____________________
4 Documentation and the record   _________  _________  _____________________
5 Controlled substances in depth _________  _________  _____________________
6 Running the standard           _________  _________  Authoritative actions
                                                        listed unprompted: [ ]
7 Communication                  _________  _________  D-23 scenarios run: [ ]
8 The business conversation      _________  _________  _____________________
9 Proactive practice             _________  _________  Forward items at the
                                                        last three debriefs: [ ]

JURISDICTIONAL BASELINE (D-2)
State ______  Established _________  Last full reverification _________

SUPERVISED SEQUENCE (2.3, "Working into independent visits")
Observed visit 1: date ______ site _____________ with _____________
Observed visit 2: date ______ site _____________ with _____________
Led visit 1:      date ______ site _____________ with _____________
Led visit 2:      date ______ site _____________ with _____________
Independent record review (four, not one):
  1 date ______ reviewer _____________ result _____________
  2 date ______ reviewer _____________ result _____________
  3 date ______ reviewer _____________ result _____________
  4 date ______ reviewer _____________ result _____________

ANNUAL CURRENCY
License reverified _________   HIPAA cycle current _________
Standard changes reviewed _________
Own records re-read (two): dates _________ / _________  notes ref ______
```

This sheet is the pharmacist's own file and it stays theirs. TOM MMS holds the facility-facing education records; the record of who trained the pharmacist is kept by the pharmacist, which is where it belongs.

KNOWN LIMITATIONS

Stated because a document that claims none is hiding them.

- This is a standard and a curriculum, not legal advice, and it says so where it matters. Where a determination has legal weight, the source is the current rule text and counsel.
- The LTC variant in Part 7 is a working variant: the visit structure, the review method, and the survey lens, borrowing the ASC form set rather than shipping its own. It says so plainly.
- State detail is deliberately absent, per A.3.1. The method ships instead.
- Regulatory citations are current as of the document date. Rules change, and the A.4 annual review exists because they do.
- The forms in Appendix C are minimum viable records, not the only correct formats. Adapt them.
- The handouts in Appendix D state the standard’s own rules and defer to the jurisdictional baseline and facility policy wherever a state could differ. A handout is not a citation.
- Software operating instructions are deliberately absent. The TOM MMS role manuals (Pharmacist, Nurse, Admin, Auditor) carry them, and they are revised with the application rather than with this standard.
- The figures are specified in text and await design rendering. The text versions are the spec.

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