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Regulating Safe Pharmacy Practice Requires Scrutiny of Who Controls Staffing, Workload, and Professional Discretion: Connecting Organizational Decisions to Accountability for Patient Safety

Lucas Meyer[1]*, Aisha Khan[2], Peter Nagy[3]

[1]Department of Health Economics and Pharmaceutical Policy, University of Amsterdam, Amsterdam, Netherlands.

[2]Department of Pharmacy Administration and Health Economics, Lahore University of Management Sciences, Lahore, Pakistan.

[3]Department of Pharmaceutical Policy and Health Financing, Corvinus University of Budapest, Budapest, Hungary.

***E-mail** ✉ lucas.meyer@uva.nl

Abstract

Patient-safety regulation in pharmacy commonly places substantial responsibility on individual pharmacists while many conditions that shape safe practice are determined elsewhere. Staffing establishments, skill mix, workload allocation, performance targets, workflow design, information access, and the practical room to exercise professional judgment may be controlled by owners, corporate structures, managers, regulators, or combinations of these actors. This article develops a Regulatory-Governance Model of Control and Accountability for examining that mismatch. Drawing on contemporary evidence concerning community-pharmacy safety climate, workforce conditions, workload, professional autonomy, organizational governance, and regulation, the analysis distinguishes legal responsibility from practical control, resource authority, target-setting power, professional discretion, oversight, and sanction capacity. The central claim is conditional: organizational scrutiny becomes necessary when an actor is held responsible for preventing a safety problem but lacks realistic authority or resources to alter the conditions producing it. The model consequently directs regulatory attention upstream from isolated practitioner conduct toward the distribution of decision rights that configure pharmacy work. It also preserves countervailing explanations, including individual competence, professional agency, local adaptation, and role negotiation. Regulatory accountability is strongest when responsibility is aligned with demonstrable capacity to change the safety-relevant condition.

Keywords: Pharmacy regulation, Patient safety, Staffing, Workload, Professional discretion, Corporate accountability

Introduction

Community-pharmacy safety is routinely expressed through the conduct of individual professionals, yet the conditions in which that conduct occurs are organizationally produced. A systematic review of patient-safety culture in community pharmacies identified staffing, work pressure, and pace among the recurrent areas requiring improvement, indicating that safety climate cannot be understood solely through individual technical competence [1]. More recent national evidence likewise shows that pharmacy safety climate remains measurable at the organizational level and varies across practice environments [2].

Incident data strengthen the case for examining the work system. Finnish community-pharmacy reports show that dispensing errors arise from heterogeneous contributing circumstances rather than a single failure mechanism [3]. At the policy level, Finland's national medication-safety programme illustrates how community pharmacies can

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be connected to incident learning, designated safety responsibilities, and broader safety infrastructure [4]. Such arrangements move regulatory attention from the isolated event toward the conditions under which events are produced, detected, reported, and corrected.

This shift also changes what should be expected from regulators. Pharmacy regulatory authorities exercise public-interest functions whose legitimacy depends partly on accountability, independence, transparency, and institutional trustworthiness [5]. A regulator that assesses practitioner conduct while leaving the distribution of safety-relevant control unexamined risks attributing responsibility at the wrong organizational level. The relevant question is consequently not only who performed the task, but who had practical power to alter the staffing, workload, targets, resources, discretion, and oversight conditions surrounding it.

Patient-safety accountability and the problem of organizational control

Organizational control refers here to the practical ability to alter a safety-relevant condition within the time and decision horizon in which that condition matters. Control requires more than formal status. It may depend on access to resources, permission to change work allocation, authority to suspend or modify targets, capacity to redistribute tasks, or the ability to authorize a safer course of action.

Community-pharmacy evidence supports treating these conditions as analytically consequential. Organizational characteristics have been associated with safety climate and related quality outcomes across community pharmacies, demonstrating that the setting in which pharmacists work contributes information beyond individual professional attributes [6]. Comparable evidence from other healthcare sectors also links work environment and clinician well-being with perceived safety and care quality, although hospital findings cannot supply pharmacy-specific effect estimates [7]. Their relevance lies at the mechanism level: professional responsibility is enacted through a work system.

That work system is adaptive. Health services operating under pressure commonly alter routines, redistribute work, defer activities, intensify prioritization, or improvise around constraints [8]. Adaptation can protect safety, but it can also conceal the extent to which routine performance depends on compensatory effort. Community pharmacists themselves identify company climate, workflow arrangements, and disciplinary or performance pressures as relevant to whether work can be performed safely [9]. Regulation that observes only the final dispensing act may consequently miss the organizational decisions that created the conditions requiring adaptation.

The regulatory problem is thus one of attribution. Individual accountability remains appropriate where a pharmacist possesses relevant authority, information, competence, and discretion yet acts unsafely. A different governance problem arises when responsibility is assigned to the pharmacist while practical control over the condition sits elsewhere. The following sections separate three major control domains—staffing, workload and targets, and professional discretion—before examining how those domains are distributed across organizational actors.

Who controls staffing?

Staffing control includes authority over pharmacist numbers, technician support, skill mix, scheduling, vacancy management, task allocation, and the capacity to replace or supplement staff when service demands change. Treating staffing as headcount alone obscures these distinctions. In community-pharmacy surveys, inadequate staffing has emerged as a prominent reported source of work stress and difficulty providing care [10]. Contemporary workforce evidence also shows that pharmacists divide their time among a growing range of dispensing, clinical, administrative, and service activities [11]. Staffing adequacy must therefore be evaluated relative to the work that the available workforce is expected to absorb.

Support staff are part of the same control problem. Pharmacy technicians contribute to operational capacity, but retention is influenced by role recognition, organizational commitment, career opportunity, and sector-specific working conditions [12]. A pharmacist may carry professional responsibility for safe service delivery without controlling recruitment, technician establishment, retention policy, or scheduling decisions that determine whether sufficient support is available.

Workforce strain provides further reason to avoid a simple numerical staffing rule. Pharmacists' compassion fatigue and professional satisfaction vary with characteristics of their work setting and exposure [13]. Job-demands–resources research likewise indicates that control, support, and other job resources condition how demands relate to burnout and professional fulfilment [14]. The regulatory implication is not a universal

pharmacist-to-prescription threshold. It is a requirement to identify who can change the workforce configuration when demand and available capacity become persistently misaligned.

Staffing accountability should accordingly follow change authority. The pharmacist responsible for a shift may control moment-to-moment deployment but lack authority to create posts, authorize overtime, alter opening hours, or redesign the skill mix. A manager may control schedules while a corporate owner controls the staffing budget. Regulatory analysis becomes more precise when these differences are made visible.

Who controls workload and targets?

Workload is produced by more than the number of prescriptions. It includes task volume, service mix, interruptions, administrative obligations, queues, performance metrics, time expectations, competing priorities, and the amount of work transferred into or out of the pharmacy. Job-demands–resources research in community pharmacy shows that practical and emotional demands operate alongside workplace and institutional resources [15]. The regulatory significance lies in the configuration: similar demand can have different consequences when workers possess different resources, control, support, and recovery opportunities.

The relationship between workload and safety is also conditional. During the COVID-19 period in Sweden, many pharmacists reported increased workload and worsened working conditions, yet a substantial proportion still perceived patient safety as unaffected [16]. That discordance matters theoretically. It prevents a regulatory model from assuming that high workload automatically produces unsafe care. Adaptation, experience, teamwork, prioritization, and temporary redistribution may sustain performance for some period or in some settings.

Certain sources of demand are nevertheless organizationally configurable. Interruptions and distractions in pharmacy practice affect perceived workload, performance, waiting time, and the cognitive organization of dispensing work, while the evidence on interventions remains heterogeneous [17]. Telephone traffic provides a concrete example of workload relocation. Introducing a centralized call centre in an academic health-system pharmacy network was followed by improvements in several safety-culture domains [18]. A related evaluation found lower perceived workload in the participating pharmacies after implementation, while some workload was transferred to call-centre staff [19]. The relevant governance lesson is the redistribution itself: work can be moved by organizational decision.

Targets deserve separate scrutiny because they convert organizational priorities into local demands. Volume expectations, service targets, administrative measures, waiting-time goals, commercial objectives, and performance monitoring can influence what receives attention during constrained periods. Qualitative evidence from community pharmacists describes under-resourcing and administrative burden as factors affecting well-being and the experience of professional work [20]. A target may be formally compatible with safe practice yet become safety-relevant when the person accountable for clinical work lacks authority to slow, defer, refuse, or escalate competing demands.

Regulators should therefore trace workload upstream. Inspection should ask who created the target, who can suspend it, who can authorize additional resources, where displaced work goes, and whether local managers or pharmacists can modify operational expectations when safety margins narrow. Those questions differ materially from asking whether the pharmacist coped successfully on the day of inspection.

Who controls professional discretion?

Professional discretion is the usable authority to apply judgment within legitimate standards of practice. It includes the ability to prioritize competing clinical tasks, seek clarification, delay a questionable process, escalate concern, adapt counseling, refuse unsafe shortcuts, and make professionally justified departures from routine workflow. Formal responsibility does not establish that such discretion is practically available.

Recent theoretical work characterizes pharmacist autonomy as independence exercised within interdependence: employment relationships, professional norms, organizational expectations, and societal obligations all shape what pharmacists can actually decide [21]. Retail-pharmacy research similarly distinguishes technical or professional autonomy from managerial autonomy, demonstrating that responsibility for professional work can coexist with limited control over organizational conditions [22].

Practitioner agency still matters. In a national Japanese community-pharmacy study, higher assertiveness was associated with experience of pharmacist-led deprescribing [23]. Such findings provide an important rival explanation for apparent under-enactment:

sometimes the relevant difference lies partly in whether a practitioner uses available discretion. Regulatory analysis should therefore determine whether authority existed before concluding that it was withheld.

Standards themselves can either support or constrain discretion. Medication-counseling scholarship has argued that greater standardization may improve consistency while still requiring sufficient flexibility for patient-specific interaction [24]. The objective is accountable discretion: practitioners need room to respond to clinically relevant variation, while regulators and organizations retain legitimate expectations concerning competence and safe process.

Relational conditions further shape whether nominal authority can be exercised. Ethnographic work on pharmacists' participation in interprofessional settings shows that trust, behavioral patterns, expectations, and social rules can affect actual participation [25]. Although hospital ward rounds are not equivalent to community pharmacy, the mechanism is relevant: usable authority can depend on whether surrounding actors recognize and support its exercise.

Professional discretion must consequently be separated from unrestricted independence. The governance question is whether the pharmacist possesses sufficient legitimate room to act on a safety concern and whether exercising that judgment carries organizational penalties, target conflicts, or escalation barriers that effectively narrow the formal authority.

Distribution of authority across owners, managers, pharmacists and regulators

Authority over safe pharmacy practice is distributed rather than concentrated in one role. Regulators establish legal and professional expectations and may determine whether practice is governed through explicit task rules or broader standards of care. Contemporary discussion of standard-of-care regulation illustrates how regulatory systems can place greater emphasis on competence and professional judgment instead of exhaustive bright-line permission lists [26]. Such a shift increases the importance of knowing whether professionals possess the organizational conditions needed to exercise that judgment.

Owners and corporate principals commonly control capital, staffing budgets, opening models, technology procurement, performance systems, and high-level operational priorities. Local managers may translate those choices into scheduling, task assignment, workflow, supervision, and local escalation. Owner-level research during the pandemic also shows that shared decision-making and external collaboration are organizational practices with differentiated consequences rather than interchangeable management activities [27].

Organizational control cannot be inferred simply by aggregating employee attitudes. Organizational culture is multidimensional and shaped by structures, practices, internal relationships, and external forces; reducing it to an individual perception score creates level-of-analysis error [28]. The same caution applies to authority. A pharmacist can perceive substantial freedom in one clinical task while lacking control over staffing or throughput. A manager may appear to control workload while being bound by corporate targets. A regulator may impose professional obligations while lacking direct authority over corporate staffing decisions.

Context also alters whether formal authority is enacted. Realist evidence concerning pharmacist integration shows that outcomes emerge through combinations of context and mechanism, including trust, invitation, stakeholder engagement, and local arrangements [29]. Authority should therefore be mapped as a set of usable control rights rather than a hierarchy inferred from job titles.

The distribution relevant to patient-safety accountability can be summarized as follows.

Table 1. Distribution of safety-relevant control rights across pharmacy actors

Actor locus	Staffing and resource authority	Workload and target-setting power	Usable professional discretion	Oversight, sanction, or change capacity	Primary accountability exposure	Control–accountability question
Owners / corporate principals	May determine establishment, budgets, technology,	May define commercial, productivity, service, or	Usually indirect; can expand or constrain the conditions in	Can redesign organizational systems, change	Corporate governance, system design,	Did this actor control the upstream condition that a

	operating model, and high-level resource allocation	network performance expectations	which professional discretion operates	budgets, alter policy, and discipline managers or staff within legal limits	resource decisions	safer local response could not realistically change?
Pharmacy managers / supervisors	May control rota construction, local deployment, task mix, escalation for additional staffing, and daily resource use	Translate higher-level targets into local priorities and workflow; may have variable power to suspend or modify them	Can protect, facilitate, or constrain pharmacists' room to exercise judgment	Can supervise, redistribute work, escalate concerns, and implement some local corrective actions	Local work organization and supervisory decisions	Was the manager able to change the condition, or only administer a constraint imposed elsewhere?
Pharmacists / professional staff	Usually limited control over establishment and budget; may influence immediate task allocation	Often experience workload and targets without setting them; may control prioritization within a shift	Direct professional responsibility for clinical judgment where practical authority exists	Can detect, document, refuse, clarify, escalate, and adapt within permitted scope	Professional conduct, competence, judgment, and response to identifiable risk	Was sufficient information, authority, time, and organizational permission available to act safely?
Regulators / inspectors	Usually do not staff individual pharmacies but can influence minimum expectations, governance standards, and enforcement priorities	Can examine how targets and workload interact with safe practice even when they do not set them	Define legal/professional boundaries and may protect or constrain legitimate professional judgment	Can inspect, require remediation, sanction, escalate, publish standards, and alter regulatory expectations within statutory powers	Public-interest oversight and adequacy of regulatory response	Does regulation reach the actor capable of changing the unsafe condition, or only the practitioner closest to the event?

The table makes one distinction central to the model: accountability should not be inferred directly from organizational proximity to the patient. The pharmacist may be closest to the safety event while another actor controls the condition that repeatedly produces the risk.

Accountability without corresponding control

Accountability–control misalignment exists when an actor carries substantial responsibility for preventing, detecting, or correcting a safety problem while lacking sufficient authority, resources, information, or organizational permission to alter the condition producing it. The concept does not remove individual professional accountability. It identifies circumstances in which individual accountability provides an incomplete explanation of why unsafe conditions persist.

Community pharmacists' work-related quality of life illustrates how demanding practice conditions can affect professional functioning and relationships without those conditions being reducible to personal competence [30]. Reporting systems reveal a related problem. Hospital-pharmacy evidence shows that perceptions of management action, teamwork, and staffing are associated with near-miss reporting behavior [31]. Reporting frequency is therefore partly a property of the

reporting environment, not a transparent measure of underlying event incidence.

Community-pharmacy safety-culture evidence adds an organizational pattern: safety assessments can vary with pharmacy context and ownership characteristics while staffing and work pressure remain persistent areas of concern [32]. Such associations do not prove that ownership form causes safety. They show why a regulator should test whether recurrent local problems are linked to decisions taken at another level.

Misalignment can take several forms. A pharmacist may be expected to guarantee safe throughput while lacking authority over staffing or targets. A manager may be accountable for local performance while unable to modify a centrally imposed operating model. A corporate owner may control resources yet be insulated from safety scrutiny focused primarily on individual professional conduct. Regulators may possess sanction authority but fail to collect information capable of identifying where practical control resides.

The counterfactual question is especially important: if the accountable actor had recognized the safety problem earlier, could that actor realistically have changed the condition? Where the answer is yes, responsibility and control may be congruent. Where the actor could only compensate temporarily, escalate unsuccessfully, or absorb additional risk while the decisive authority remained elsewhere, attribution requires broader regulatory scrutiny.

Development of the regulatory-governance model

The preceding analysis supports a model in which safety accountability is evaluated against the distribution of practical control, rather than inferred from professional title alone. Practical control means the realistic capacity to alter the condition relevant to the safety problem: staffing and resource availability, workload or target intensity, workflow configuration, access to information or support, usable professional discretion, or the organizational response to an identified hazard.

Formal authority and implementable capacity are already distinguishable in pharmacy practice. A global review of formally recognized advanced community-pharmacist practice found substantial variation in how expanded roles are supported, with implementation affected by factors including remuneration, access to records, and stakeholder awareness [33]. The regulatory relevance is broader than advanced practice. A professional obligation can exist on paper while the resources or organizational permissions necessary to discharge it remain incomplete.

Institutional context also determines which actors possess which control rights. Comparative analysis of community-pharmacy service development across four European countries shows that pharmacy service scope and the drivers of change differ materially across health systems [34]. Accountability rules therefore cannot assume that the same actor controls the same condition in every jurisdiction. The model must first identify the local allocation of authority.

Implementation research adds a third requirement: relevant determinants operate in combination. Community-pharmacy implementation strategies must be matched to interacting organizational conditions rather than isolated barriers considered independently [35]. This supports a configurational approach to regulatory accountability. Staffing authority, target-setting power, discretion, information access, escalation capacity, and sanction power may be distributed among several actors, and a safety problem may emerge from their interaction.

The Regulatory-Governance Model of Control and Accountability therefore uses four linked questions.

First, what safety-relevant condition requires explanation? The unit of analysis may be inadequate staffing, accumulated workload, an imposed performance expectation, constrained professional judgment, ineffective escalation, or another condition that plausibly affects safe practice.

Second, who carries responsibility for managing the resulting safety risk? Responsibility may derive from professional standards, employment duties, organizational policy, regulatory rules, or supervisory authority. More than one actor can legitimately carry responsibility for the same condition.

Third, who possesses practical control over the condition? This requires tracing decisions rather than titles. A pharmacist may control immediate clinical prioritization while a manager controls deployment and a corporate owner controls establishment and budget. A regulator may specify professional expectations yet depend on organizational actors to provide the operating conditions necessary to satisfy them.

Fourth, who can change the condition when ordinary local adaptation is insufficient? This final question distinguishes temporary coping from genuine control. An actor who can only work faster, defer lower-priority tasks, request help, or document concern does not

necessarily control the underlying condition. Change authority lies with the actor able to alter the staffing model, resource allocation, target, workflow rule, permission structure, or regulatory requirement.

The model does not assume that every mismatch produces harm. Job resources can buffer demands [14], relational conditions can enable professional participation [29], and pharmacists may retain meaningful autonomy within interdependent systems [21]. It instead identifies a regulatory configuration that becomes important when responsibility and change authority diverge.

Figure 1 represents these relationships as a multiactor governance field. It separates professional responsibility from staffing/resource authority, workload and target control, usable discretion, organizational oversight, and regulatory sanction capacity so that accountability can be traced to the actor or combination of actors capable of changing the safety-relevant condition.

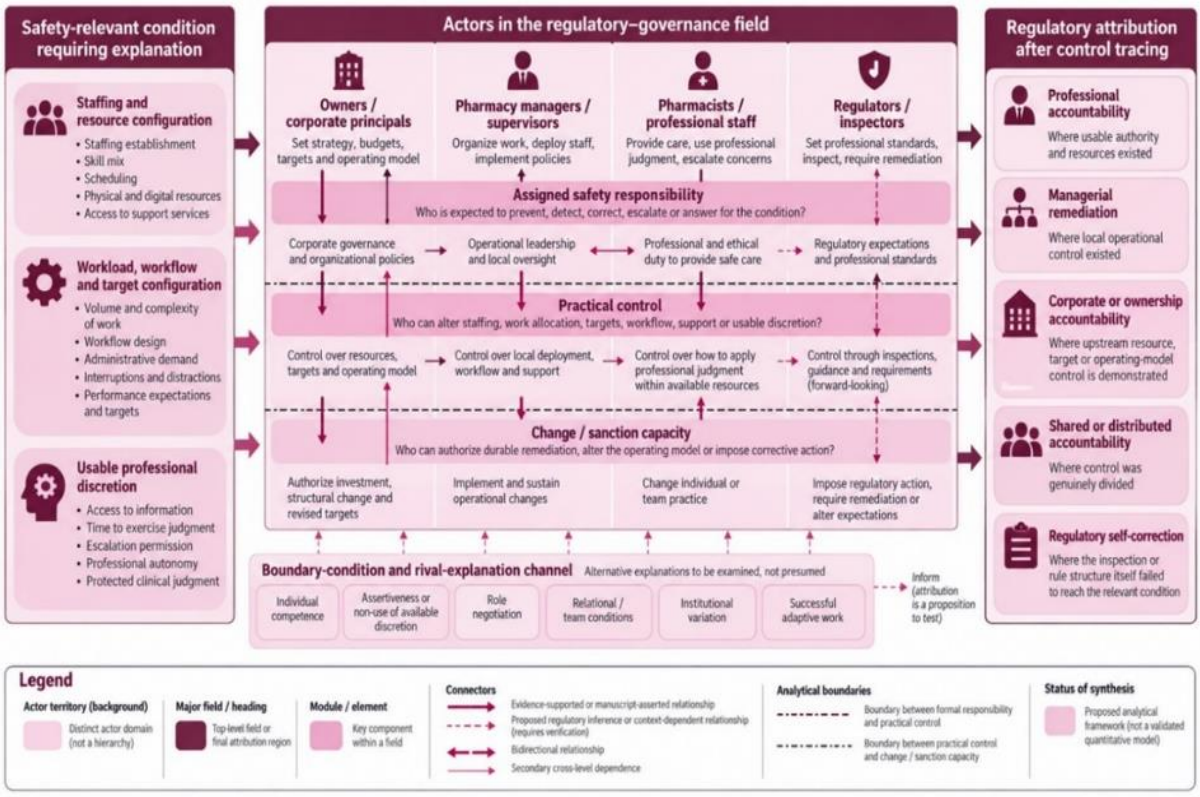

Figure 1. From safety responsibility to change authority: a multiactor governance field for pharmacy regulation

Regulatory blind spots

Regulatory blind spots arise when the information collected through inspection, incident review, or disciplinary processes cannot reveal where practical control actually resides. Practitioner conduct is visible because it occurs near the patient and is documented through prescriptions, records, counseling, and dispensing processes. Upstream decisions about budgets, target structures, staffing establishments, scheduling models, or constraints on escalation may be less visible even when they materially configure local work.

The first blind spot is role attribution. A pharmacist may appear not to use an available professional role because of organizational restriction, but professional identity and negotiation can also explain under-enactment. In primary-care teams, pharmacists have sometimes permitted other actors to define their role through relatively passive role negotiation [36]. This evidence prevents the model from assuming that every unused capability reflects upstream constraint. Inspection must distinguish authority that was absent from authority that existed but was not exercised.

A second blind spot is managerial opacity. Pharmacists may describe corporate climate, workflow pressures, or disciplinary concerns as relevant to safe practice [9], yet these influences can be difficult to reconstruct from an

isolated incident. Similarly, managerial autonomy and professional autonomy are not identical [22]. A local manager may be able to direct staff while lacking authority to change the staffing establishment or performance regime that generated the local constraint.

A third blind spot involves level confusion. Organizational culture cannot be inferred reliably from one individual's attitude or one observed behavior [28]. A regulator who sees repeated local workarounds may interpret them as individual noncompliance when they may instead be adaptations to recurrent system conditions. Conversely, the existence of organizational pressure does not establish that every deviation was compelled by that pressure.

A fourth blind spot concerns reporting visibility. Near-miss reporting varies with perceptions of management, teamwork, and staffing [31]. Community-pharmacy safety-culture ratings likewise vary across organizational contexts, with staffing and work pressure remaining important concerns [32]. A low number of reported events can therefore coexist with weak learning conditions. Absence of incident visibility should not automatically be interpreted as evidence that underlying risk is absent.

These blind spots make the regulator's evidentiary task more demanding. The relevant question is not simply whether an undesirable event occurred, but whether the regulatory record is capable of distinguishing practitioner failure, adaptive local practice, insufficient local authority, and upstream organizational control.

Table 2. What practitioner-centred inspection can miss when control sits elsewhere

Observable regulatory signal	Possible hidden control condition	Competing non-organizational explanation that must also be tested	Evidence the inspector would need to seek	Attribution error if the blind spot is ignored
Recurrent delays, shortcuts, unfinished work, or queue pressure	Staffing establishment, scheduling, service volume, or target configuration controlled above the individual pharmacist	Poor prioritization, competence deficit, or inefficient local organization	Staffing decisions, schedules, workload distribution, escalation requests, target instructions, local mitigation attempts	Treating a repeated system constraint as isolated practitioner underperformance
Pharmacist fails to exercise apparently available clinical discretion	Organizational penalty, target conflict, restrictive workflow rule, unavailable support, or manager-dependent permission	Low assertiveness, professional identity, uncertainty, or voluntary non-use of available authority	Written policy, escalation history, examples of prior decisions, managerial response, protected-discretion arrangements	Assuming either complete autonomy or complete suppression without testing practical authority
Local manager repeatedly operates with inadequate capacity	Budget or establishment controlled by corporate or ownership level	Weak local planning, poor deployment, ineffective supervision	Budget authority, vacancy approvals, staffing requests, corporate instructions, manager's delegated powers	Sanctioning the manager for a condition the manager could document but not alter
Few incident or near-miss reports	Reporting burden, weak management response, fear of consequences, insufficient time, or poor learning infrastructure	Genuinely low event frequency	Reporting process, staff perceptions, follow-up records, protected reporting mechanisms, learning actions	Equating low reporting with high safety
Repeated local adaptations or workarounds	Persistent mismatch between formal process and actual work capacity	Unnecessary noncompliance or convenience behavior	Reason for workaround, recurrence, risk assessment, whether formal process is usable under normal demand	Treating adaptive behavior as the primary problem while leaving the generating condition unchanged

Compliance with formal rules despite continuing safety concern	Rules may specify conduct without addressing staffing, resources, workload, or practical discretion	Problem may lie outside organizational control or remain clinically unavoidable	Resource authority, target-setting responsibility, workflow design, escalation capacity, system constraints	Assuming formal compliance exhausts the regulator's safety function
Corporate policy appears neutral but local risk recurs across sites	Centralized target, technology, staffing, or operating-model decision may have distributed effects	Similar local practices may have arisen independently	Cross-site comparison, central policies, decision records, implementation guidance, authority to modify conditions	Viewing repeated site-level problems as unrelated individual events

Governance tests and indicators

A regulatory-governance approach requires indicators that reveal authority, not merely outcomes. These indicators are proposed analytical tests rather than validated scales or numerical safety thresholds.

The first is the responsibility–control congruence test: for each safety responsibility assigned to an actor, inspectors should identify the decisions and resources that actor can actually control. Staffing surveys and work-activity evidence demonstrate that capacity can be observed through concrete features of practice rather than assumed from staffing titles alone [10]. Contemporary activity data likewise allow workload to be related to the tasks pharmacists are expected to perform [11].

The second is the resource-authority test: when risk is attributed to inadequate resources, who can authorize additional staffing, technology, information access, protected time, or support? Safety programmes that explicitly connect pharmacies to incident-learning infrastructure demonstrate that organizational safety resources can be deliberately created [4]. The test should therefore distinguish absence of resources from failure to use resources that were genuinely available.

Third, regulators need a target-pressure traceability test. Interruptions and competing work demands are recognized features of pharmacy practice [17]. Organizational interventions that centralize telephone work show that demand can be redistributed [18], while workload measurement confirms that reducing pressure in one location can move work elsewhere [19]. An inspector should consequently trace where the demand originated, who benefits from the target, who can suspend it, and whether mitigation simply transfers risk to another worker or location.

Fourth is the protected-discretion test. Professional autonomy operates within interdependence [21]. Regulation should examine whether pharmacists can exercise clinically legitimate judgment without avoidable organizational penalties and whether standards leave room for patient-specific professional action [24]. A pharmacist who technically possesses authority but predictably incurs sanction for using it may have less practical discretion than formal policy suggests.

Fifth is the escalation-responsiveness test. A control system should reveal what happens after a practitioner or manager identifies a safety concern. Reporting environments are partly shaped by management and staffing conditions [31]. Inspectors therefore need evidence not only that an escalation channel exists but that concerns reach an actor capable of changing the relevant condition.

Finally, the change-and-sanction reach test asks whether regulatory action reaches the actor with actual capacity to remediate the problem. Contemporary standard-of-care regulation illustrates that regulators can place greater emphasis on competent professional judgment [26]. When regulation increases reliance on judgment, however, inspection must also examine whether the surrounding organizational system permits that judgment to be exercised.

Table 3. Governance tests for locating control before assigning safety accountability

Governance test	Core inspection question	Observable indicators	Evidence of alignment	Evidence suggesting misalignment	Regulatory use

Responsibility–control congruence	Does the actor responsible for the safety obligation control the condition necessary to meet it?	Assigned duties, delegated powers, staffing authority, workflow permissions, decision rights	Responsibility accompanied by usable authority and resources	Responsibility assigned without realistic ability to alter the condition	Determines whether accountability can remain at the observed actor level
Resource-authority	Who can authorize additional capacity when existing resources become inadequate?	Budget authority, hiring approval, overtime, technology access, staffing requests, information systems	Resource holder can respond within a relevant time horizon	Local actor can identify shortage but cannot obtain or redeploy resources	Directs remediation toward the resource-controlling level
Target-pressure traceability	Who sets, monitors, benefits from, and can suspend the workload or performance expectation?	Metrics, quotas, service expectations, queue targets, productivity reports, escalation rules	Safety override is explicit and practically usable	Targets remain binding despite documented safety conflict	Identifies upstream target-setting responsibility
Protected discretion	Can pharmacists exercise legitimate clinical judgment without avoidable organizational penalty?	Override policies, refusal/escalation procedures, manager responses, examples of exercised judgment	Judgment is supported within professional standards	Formal discretion exists but is practically discouraged or punished	Distinguishes professional non-use from organizational suppression
Escalation responsiveness	Does a reported concern reach someone able and willing to change the condition?	Incident reports, escalation records, response time, corrective action, feedback	Concerns produce review and proportionate corrective action	Reporting terminates at a level lacking change authority	Tests whether the learning system has functional reach
Change-and-sanction reach	Can inspection or enforcement reach the actor whose decision sustains the unsafe condition?	Corporate policies, ownership decisions, delegated powers, regulator jurisdiction, remediation orders	Enforcement locus matches demonstrated control	Sanctions fall only on proximal practitioners despite documented upstream control	Supports proportionate practitioner, managerial, corporate, or regulatory response

These tests deliberately avoid universal numeric staffing thresholds or risk scores. Their purpose is discriminating: to identify whether responsibility and authority are aligned in the particular organizational configuration under examination.

Implications for inspection, enforcement and corporate accountability

Inspection should begin with the observable safety concern and then travel upstream until the relevant change authority is identified. National medication-safety programmes demonstrate that community pharmacies can be integrated into broader incident-learning structures [4]. Regulatory trustworthiness also depends on regulators' capacity to demonstrate that their own processes serve the public interest [5]. Inspection that repeatedly identifies practitioner deficiencies while leaving controllable organizational conditions outside its field of view risks becoming procedurally thorough but causally incomplete.

This does not require replacing professional standards with corporate regulation. Standard-of-care approaches

continue to make pharmacist competence and judgment central [26]. The model instead adds a second inquiry: whether the professional had the staffing, information, time, escalation route, and practical discretion necessary to satisfy the standard under the conditions imposed.

Enforcement should consequently distinguish local failure, distributed failure, and upstream control. Owner-level evidence shows that pharmacy organizational decisions can involve shared decision-making and external collaboration, while their consequences depend on context [27]. Organizational culture is likewise not reducible to the conduct of a single worker [28]. A recurrent problem across multiple locations should therefore trigger analysis of shared policies, resource allocation, technology, target structures, and governance arrangements before it is treated as coincidental local failure.

Corporate accountability should be evidence-based rather than presumed from ownership. Cross-national variation in pharmacy systems demonstrates that the distribution of authority differs institutionally [34]. A corporate principal should attract stronger accountability where evidence shows that it controlled the staffing establishment, target, workflow, resource, or organizational rule that generated the relevant constraint and possessed authority to change it. Conversely, a corporate relationship alone is insufficient when the decisive condition is controlled by a regulator, local professional, external health system, or another actor.

Reporting and implementation evidence further indicate that regulatory response must reach beyond policy existence. Management and staffing conditions affect reporting behavior [31], while implementation depends on interacting local determinants [35]. A corporation may therefore satisfy a formal policy requirement while producing an operating environment in which the policy cannot be used effectively.

The same discipline applies before attributing failure upstream. Role negotiation and professional identity can constrain enactment independently of formal organizational restrictions [36]. Regulators should test whether pharmacists or managers had authority they did not exercise, whether escalation was attempted, and whether the problem could realistically have been corrected locally.

Corporate accountability is therefore strongest when four conditions coincide: the organization controlled the safety-relevant condition; the condition materially constrained safer practice; the organization could reasonably have recognized or received escalation about the problem; and it possessed practical capacity to alter it. This rule ties accountability to demonstrable control while preserving legitimate professional responsibility.

Results and Discussion

This article develops a regulatory-governance account of pharmacy safety in which the allocation of responsibility is evaluated against practical control over the conditions needed for safe work. The contribution is narrower than a general claim that organizations influence safety. Community-pharmacy research already demonstrates recurring concern about staffing, work pressure, workflow, and organizational climate [1]. The theoretical addition is to treat those conditions as control rights that can be traced across actors and compared with the location at which accountability is imposed.

The strongest evidence supports scrutiny of organizational conditions, but it does not establish deterministic relationships. Cross-healthcare evidence links work environment and professional well-being with perceived care quality and safety [7], while research on pressured services demonstrates that adaptation can sustain performance through multiple strategies [8]. Pharmacy-specific evidence is similarly conditional. During the Swedish COVID-19 period, substantial increases in workload coexisted with reports from many pharmacists that patient safety was unaffected [16]. High demand is therefore a signal for inquiry, not proof of unsafe practice.

Professional autonomy creates another boundary. Pharmacists' discretion is inherently relational and institutionally embedded [21]. An accountability-control model would be distorted if every undesirable professional decision were explained by organizational constraint. Individual competence, assertiveness, interpretation of professional standards, willingness to escalate, and use of available authority remain relevant.

The model also cannot determine legal liability. Legal responsibility depends on jurisdiction-specific statutes, contracts, professional standards, corporate law, regulatory powers, and factual causation. The governance model instead specifies an evidentiary question that should precede strong attribution: who controlled the condition and who could have changed it?

Role negotiation constitutes a particularly important rival mechanism. Pharmacists can participate passively in defining their own professional role, allowing others to

shape expectations even without explicit prohibition [36]. Regulation should therefore avoid two symmetrical errors: blaming the practitioner for every unsafe condition, or treating every constrained act as evidence of upstream organizational control.

The practical value of the model lies in what it changes during inspection. Staffing becomes more than a headcount. Workload becomes more than prescription volume. Autonomy becomes more than formal scope. Reporting becomes more than event counts. Corporate accountability becomes more than ownership status. Each is converted into an inquiry about decision rights, usable resources, escalation, and change authority.

Future research should test whether these distinctions improve regulatory diagnosis. Empirical work could examine whether responsibility–control incongruence predicts recurrent safety concerns, whether inspectors can reliably identify change authority, and whether remediation directed toward the controlling actor produces different organizational responses from practitioner-only intervention. Such studies would require careful multilevel designs because organizational, professional, and regulatory influences cannot be inferred from one level alone.

Conclusion

Safe pharmacy practice depends partly on individual competence and professional judgment, but those responsibilities are exercised inside organizational systems that distribute staffing authority, workload and target control, resources, discretion, oversight, and sanction power across different actors.

Regulatory accountability should therefore be allocated with attention to practical control. When pharmacists or managers possess the authority and resources needed to respond safely, responsibility can appropriately remain close to their decisions. When the decisive condition is controlled elsewhere, regulation should trace the problem upstream rather than treating proximity to the patient as proof of control.

The resulting claim is conditional rather than absolute: scrutiny of owners, managers, corporate structures, or regulators is warranted when they demonstrably control a safety-relevant condition that the actor held responsible cannot realistically change. Aligning accountability with change authority offers a more discriminating basis for inspection, enforcement, and corporate responsibility while preserving legitimate professional accountability.

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