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### HEALTH LAW: PEER-REVIEWED ARTICLE

#### How Might Antibiotic Stewardship Programs Influence Clinicians' Autonomy and Organizations' Liability?

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##### Abstract

Federal and state governments mandate some health care organizations to implement antibiotic stewardship programs (ASPs). Some early adopters developed model ASPs that have helped set industry standards; other benchmarks will likely be forged in subsequent regulation, legislation, and jurisprudence. This article considers how ASP designs can affect professional autonomy, especially of frontline antibiotic stewards who are usually physicians and pharmacists. This article also considers how ASP development and implementation might influence standards of care and malpractice liability.

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##### Stewardship Programs

Antibiotic stewardship programs (ASPs) aim to track the use of antibiotics, to encourage data sharing by providing high-level expertise on these drugs, and to improve care by guiding appropriate prescribing practices.<sup>1</sup> Although these programs are designed to help clinicians and have been shown to improve patient outcomes, reduce costs, and prevent the development of antibiotic resistance,<sup>1</sup> some stewardship interventions might be perceived as limiting clinician autonomy and raise complex, as-yet unsettled questions of malpractice liability for primary clinicians, ASPs and their personnel, and health care institutions.<sup>2</sup> Without clearer prospective laws, regulations, or other standards, the inevitable controversies arising from ASP implementation—with implications for clinician autonomy and the professional and medico-legal **allocation of responsibility** between primary clinicians and ASPs and their personnel—will be shuttled to other fora, such as trial courts that litigate malpractice claims on an ad hoc, case-by-case basis.<sup>3</sup> This article explores existing legal authorities concerning antibiotic stewardship and analyzes the implications that ASP implementation might have for clinician autonomy and malpractice liability, especially in light of the potentially unpredictable ways that rules or standards derived from malpractice suits may develop.

### **Responsibility for ASPs**

Federal rules and national standard-setting organizations have encouraged the development of ASPs, but many of the debates on the contours of ASPs occur outside the government and its regulatory agencies. In a series of rules in the 2010s, the Centers for Medicare and Medicaid Services (CMS) essentially mandated ASPs in most inpatient and long-term care settings, including one notable final rule published on September 30, 2019.<sup>4,5</sup> These rules were sparse on detail but mandated basic program infrastructure and activities. CMS did notably express in its September 2019 rule that it sought to “build flexibility into the regulation by proposing language that requires hospitals to demonstrate adherence to nationally recognized guidance and guidelines, rather than any specific guidance, guideline, or set of guidelines, for best practices in infection prevention and control and for implementing antibiotic stewardship programs.”<sup>4</sup> Although certain hospitals “may have less resources available,” CMS did “encourage” those hospitals “to utilize the existing available resources to ensure the antibiotic stewardship requirements are met” because “antibiotic stewardship is no less important in these settings.”<sup>4</sup>

Standard-setting organizations and quasi-governmental actors have provided much more detail on guidelines for implementing ASPs. For instance, the Joint Commission has outlined the structure and resources that should be devoted to ASPs in its 2023 revisions to its standards.<sup>6</sup> Furthermore, the Centers for Disease Control and Prevention (CDC),<sup>7</sup> Society for Healthcare Epidemiology of America,<sup>1</sup> and Infectious Diseases Society of America<sup>1</sup> have provided guidelines and resources for programs, some of which are mentioned in Medicare’s guidance as sources of assistance.<sup>4</sup>

That said, ASPs represent only one aspect of the federal and national response to the problem of antibiotic resistance—and thus only a part of the law addressing these areas. The federal government is often interested in information acquisition from ASPs,<sup>8</sup> and, to that end, CMS required hospital antimicrobial use and resistance data to be shared with the CDC starting in 2024.<sup>9</sup> Moreover, complementing the goal of ASPs, other parts of the federal government have focused on ensuring a pipeline of new antibiotic candidates to help overcome resistance, targeting novel biological threats, and preventing the widespread use of antibiotics in animals.<sup>10,11</sup>

Given that the federal government and national organizations are concerned with the broader problem of antibiotic resistance and less suited to account for multiple contingencies and local practice settings, state regulators will likely provide more detailed guidance to health care institutions—and may provide the fora to address novel issues and problems for ASPs. To be sure, some states have followed the lead of the federal government and have mandated antimicrobial stewardship regional advisory committees,<sup>12</sup> and others have gone further to protect against the development of antibiotic resistance.<sup>13</sup> But traditional state malpractice liability may still become an important method to regulate ASPs where regulatory voids exist.

### **Malpractice Liability**

Malpractice litigation is a familiar legal mechanism by which health care practitioners and institutions can be held accountable for alleged medical errors. Indeed, **malpractice cases** can themselves serve as a form of regulation by establishing legal precedent that may influence future medical practice. Briefly, the elements of a malpractice claim consist of a duty of a health care practitioner or institution to a patient, a breach of that duty, and an injury to a patient caused by that breach of duty. Breach of duty is

determined by reference to an established standard of care: how similarly-situated practitioners would act in similar clinical circumstances.<sup>14</sup>

The decision making of ASPs is not immune from malpractice exposure. Since ASPs can influence patient care and outcomes, it would be reasonable to believe that ASPs would be liable for those actions and subject to malpractice litigation.<sup>3</sup> However, because members of ASPs often do not interact directly with patients and because a clear standard of care has yet to be established by case law, each one of these elements could be contested.

ASPs and their activities come in many forms, and the different ASP roles implicate different liability and clinician autonomy issues, including prior authorization of selected antibiotics, prospective audit and feedback, benchmarking, medical record clinical decision support, formulary restriction, dose optimization, assistance with parenteral to oral conversion, and guideline development.<sup>1</sup> As a result, there is a kaleidoscope of different lenses through which courts could view ASPs and their activities—and thus influence how ASPs are integrated into preexisting health care infrastructure. Although each issue would carry a different liability implication, health care institutions would focus on balancing potential legal exposure and clinical autonomy.

### **Stewardship and Sources of Liability**

There are several possible patient scenarios, of varying plausibility, out of which a malpractice suit might arise<sup>15,16,17</sup>: (1) patients who allege that they were inadequately treated because of an antibiotic or lack thereof, (2) patients who allege that they suffered harmful side effects because of an antibiotic, and (3) patients who allege that they suffered an infection from a resistant organism that would have otherwise been preventable but for insufficient antibiotic stewardship.

First, patients might allege that they were inadequately treated because they were prescribed an inappropriate antibiotic or because they were not prescribed an antibiotic at all. There are at least 2 variations of this scenario: a patient who is prescribed an antibiotic that an ASP recommended and a patient who is prescribed a different antibiotic by a primary clinician notwithstanding the ASP's recommendation. In the first variation, the patient might sue the ASP and its personnel because their recommendation was followed by the primary clinician who may have otherwise prescribed a more appropriate antibiotic. In the second variation, the patient might sue the primary clinician who failed to heed the ASP's recommendation, potentially causing harm. In either case, the patient might sue the health care institution for failing to design its ASP in a way that might have prevented the alleged harm. Second, and relatedly, patients might allege that they suffered harmful side effects because of an antibiotic that they were prescribed. The possible sources of malpractice liability are similar to the first scenario and its variations. Finally, patients might allege that they suffered an infection that would have otherwise been preventable in the presence of more effective antibiotic stewardship.

These scenarios are more than theoretical sources of liability. One such scenario may occur directly as the result of antibiotic use in a single patient, the most likely of which may be the patient's acquiring a *Clostridioides difficile* (*C difficile*) infection. Because the risk of this infection is increased by health care and antibiotic exposure,<sup>18</sup> the prescriber may be held liable for the infection if the antibiotic prescribed was inappropriate. Similar arguments could be made for other resistant organisms in which infection acquisition is

associated with antibiotic use. Many of these resistant organisms, such as *C difficile*, can also spread horizontally to multiple patients within a health care facility. Moreover, higher rates of antibiotic use in health care units are associated with higher rates of *C difficile* on those units.<sup>19</sup> Even if a patient did not receive an antibiotic, it could be argued that their acquisition of an antibiotic-resistant infection was the result of insufficient antibiotic stewardship. Such a theory of malpractice liability might be the basis of a proceeding brought by individual patients or might be brought by several or many patients as, for example, a mass tort or class action.

### **ASPs and Their Legal Implications**

There are at least 4 possible conceptualizations of ASPs and their roles in a health care institution: (1) as a consultant for a particular patient; (2) as a guardian of scarce antibiotic resources; (3) as an educational resource providing general antibiotic guidance and serving as a repository of useful clinical information related to appropriate antibiotic prescribing; and (4) as a mechanism by which to aggregate, organize, and develop relevant resources to guide antibiotic use. These conceptualizations are not mutually exclusive. Each conceptualization, however, might imply different relationships between ASPs and their members, be they antibiotic stewardship personnel, on one hand, or primary clinicians, on the other. Furthermore, each conceptualization may give rise to several possible sources of malpractice liability for the ASPs, their personnel, primary clinicians, and health care institutions.

*ASPs as consultants.* The ASP may be viewed as acting as a sort of consultant, providing an opinion on a particular patient care issue, such as when an ASP provides a prospective audit and feedback by making recommendations to primary clinicians based on information ASP personnel review in the medical record, local antibiotic susceptibility data, and applicable guidelines. This ASP role might be akin to that of a pathologist or radiologist who does not directly interact with a patient but who nonetheless opines on a particular aspect of care. Ignoring these trusted consultants might carry medical and legal risks for primary clinicians. Because most primary clinicians cannot independently assess studies with the same degree of rigor as specialists, clinicians who consult ASPs sacrifice some of their autonomy. However, primary clinicians do have some capacity to disagree with a specialist if the reasons are well founded and well documented in the medical record, especially because primary clinicians' proximity to the patient confers a unique vantage point. Indeed, good documentation by ASPs and their personnel—as well as by primary clinicians—and explaining and justifying assessments and recommendations might mitigate possible malpractice liability while also promoting clinician autonomy, especially in the event of disagreements.<sup>20</sup> On the other hand, minimizing clinicians' ability to disagree with specialists or the ASP could channel liability to one decision maker—namely, to a specialist or to the ASP.

Open questions remain as to the precise nature of the consulting role of ASPs. For example, might ASPs be considered legally analogous to a formal infectious disease consultation? Or might ASPs be considered more analogous to something commonly known as a “curbside” consult, as when one clinician asks another a question in passing about a specific patient? Even if ASPs are found to function in a legally analogous way to curbside consults, such curbside consults have attracted some scrutiny by legal authorities, given that they may influence patient care.<sup>21</sup>

Absent further prospective legal or regulatory clarity, the question of the precise nature of the consulting role of ASPs would likely be resolved—and its implications for where

and when liability exists clarified—through the piecemeal, case-by-case development of the law through malpractice suits. Indeed, ASPs-as-consultants might give rise to liability for primary clinicians for failing to heed ASP guidance, for ASPs and their personnel for flawed recommendations, or for health care institutions regarding their institutional protocols and policies for ASPs and their relationship with primary clinicians.

*ASPs as gatekeepers.* The ASP may be seen as guarding a specialized or scarce resource when it sponsors prior authorization systems—that is, when, due to factors such as drug cost and spectrum of activity, clinicians require approval from ASP personnel to use certain antibiotics. In general, “[t]he intent of prior authorizations is to ensure that drug therapy is medically necessary, clinically appropriate, and aligns with evidence-based guidelines.”<sup>22</sup> The ASP’s role as gatekeeper is much like that of an oncologist selecting chemotherapeutic agents for a targeted cancer treatment plan or that of an intensivist faced with a limited number of critical care beds whose role is to improve outcomes for individual patients and to maximize benefit for the entire population of patients eligible for these resources. Primary clinicians not trained in these specialties typically do not solely decide cancer treatment plans or triage critically ill patients. Analogously, primary clinicians may not be expected to have as much expertise in antibiotic prescribing and stewardship as ASP personnel. In cases in which ASPs act as gatekeepers, patients might be denied access to an antibiotic or given another one that their primary clinician might not otherwise have prescribed had it not been for an ASP’s recommendation. The existence and distribution of malpractice liability in this regard—among primary clinicians, ASPs, and health care institutions—would likely depend on several factors, including whether primary clinicians have discretion to heed or disregard an ASP’s recommendations or whether an ASP’s recommendations are binding rather than merely suggestive. Furthermore, it might be prudent for health care institutions to consider implementing **clear escalation protocols** if a primary clinician should disagree with the recommendations of an ASP, perhaps a recommendation to formally consult an infectious disease specialist or a physician-director of the ASP itself.

*ASPs as educators.* The ASP can act as an educational resource by providing general antibiotic guidance and serving as a repository of clinical information related to appropriate antibiotic prescribing and stewardship protocols. For example, a clinician may ask physicians or pharmacists from the ASP for advice on choosing an oral antibiotic that is equivalent to an intravenous antibiotic or for a good choice to treat pyelonephritis in a patient with a specific antibiotic allergy. Such queries would be different from a consultation because these questions may not require ASP personnel to review a particular patient’s medical record if they are framed in theoretical or hypothetical terms, not unlike a case vignette. These questions may have consensus answers that may not be accessible to or remembered by busy clinicians.

In these situations, seeking answers to hypothetical or case vignette questions that do not directly refer to a patient being cared for at the moment differs from a formal consultation with infectious disease specialists, which might also entail seeing a specific patient or reviewing a patient’s medical records in order to answer a specific and potentially treatment-guiding question. These scenarios likewise differ from the ASP consultation role as well as from patient-specific curbside consults discussed above. However, in these scenarios, ASPs might still enhance primary clinicians’ autonomy by providing relevant and specialist knowledge and thereby facilitating the growth of primary clinicians’ fund of knowledge. The precise implications clinicians’ subsequent actions might have for malpractice liability—for primary clinicians themselves, for ASPs

and their personnel, or for health care institutions—will, of course, in part, depend on the evolving status and precise medico-legal definition of curbside consults, and, once again, on the institutional practices and policies regarding how ASPs work at a given institution, their relationship with primary clinicians, and the nature—suggested or required—of their recommendations.

*ASPs as aggregators.* ASPs can provide mechanisms by which to aggregate and organize relevant information regarding antibiotics, including local and national guidelines. In this role, ASPs might also contribute to developing institutional guidelines and, therefore, helping to inform the local standard of care by adapting guidelines from public health authorities or professional societies. Here, failure to follow institutional or other relevant local or regional practice guidelines without compelling clinical reasons, such as a novel situation or unique patient factors, could lead to liability exposure for primary clinicians. Yet courts have been clear that guidelines do not automatically set the standard for malpractice,<sup>23</sup> so guidelines can also be seen as channeling autonomy by proscribing some actions while maintaining space for clinicians' discretion in specific clinical situations. That said, failure to follow guidelines without sufficient documented justification can be a basis for liability.

### **Evolving ASPs**

Given these different conceptions of ASPs, health system leaders have a menu of options to tailor an ASP to the local liability environment and to clinician autonomy considerations. However, each conception of an ASP has its own malpractice and autonomy implications, as do different institutional choices regarding the design of an ASP. The lack of clear prospective legal requirements concerning the structure of ASPs, including the nature of their day-to-day functions in a health care institution and their relationships with existing care protocols, permits variability in ASP design, implementation, and administration.

Institutions, such as hospitals, will therefore need to create their own protocols, guided by the general direction provided by relevant laws and regulations, including national guidelines and regulations from relevant authorities. These choices will have implications for clinician and institutional responsibility and clinician autonomy and, therefore, for malpractice liability. Indeed, such lack of clarity and the implied flexibility means that many questions about the evolving roles of ASPs—and their relationships with clinicians—may end up being clarified through the case-by-case process of malpractice-based litigation against primary clinicians, ASPs and their personnel, or health care institutions.

It is thus crucial for health care institutions and health care practitioners involved in the design, implementation, and administration of ASPs to consider possible theoretical roles of ASPs and possible theoretical sources of malpractice liability that might arise from these different roles in the context of antibiotic prescribing in order to mitigate risks associated with malpractice liability while still preserving clinician autonomy and providing optimal patient care. Such considerations will ideally evolve in light of ongoing developments concerning best practices for ASP design and implementation and in light of new legal and regulatory requirements arising through malpractice litigation and otherwise. For instance, in thinking about the ASP as a consultant, program designers need to consider where to draw the line between ASP involvement and the need for a formal infectious disease consultant. For an ASP as aggregator, vigilance regarding new developments that may require updates to guidance is required. Of course, malpractice

is not the only legal consideration in ASP design and its implications for individual practitioner autonomy; for instance, scope of practice rules affect how and through whom ASPs implement recommendations. Nonetheless, evolving legal mandates and institutions will likely contribute to the ongoing and evolving conversation concerning the proper role and function of ASPs.

Malpractice litigation by its very nature will develop new rules and standards on an ad hoc, case-by-case basis; indeed, different courts in different jurisdictions may adopt different and perhaps even conflicting rules or standards, which, in general, is how the common law tends to develop. While such a manner of legal development has its own merits, it also has its flaws, not the least of which is the lack of clarity, consistency, and predictability. As such, to avoid the malpractice system and its possible vagaries from dominating the development of rules concerning ASPs, health care institutions, physicians, and other stakeholders should consider working toward clearer national standards and rules. In the meantime, however, those same institutions and clinicians will need to build and reform their ASPs while keeping possible malpractice liability in mind, which will require thinking seriously about possible sources of that liability and their implications for care team protocols and clinician autonomy.

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