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Electronic Prior Authorization for Prescription Drugs — Challenges and Opportunities for Reform

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On December 6, 2022, the Centers for Medicare and Medicaid Services issued a proposed rule to streamline the electronic prior-authorization process for medical services in the Medicare Advantage program.[1] The rule doesn't address outpatient prescription drugs covered under Medicare Part D, the program responsible for the bulk of Medicare drug spending. We believe congressional and regulatory attempts to modernize and streamline the prior-authorization process should include outpatient prescription medications, although such efforts would face many implementation challenges.

Prior authorization refers to the process whereby a clinician is required to obtain prior approval from a payor (e.g. a health plan) before a medical service can be covered. Prior authorization for prescription drugs serves an important purpose: it ensures that high-cost or high-risk medications are dispensed only to patients for whom they are clinically indicated. In some cases, prior authorization (along with other formulary-based tools) may give health plans leverage to negotiate larger discounts or rebates from drug manufacturers, thereby lowering overall costs for the payor. Despite the benefits of prior authorization for controlling prescription-drug spending and discouraging low-value care, however, the prior-authorization process is often burdensome for clinicians and has consequences for patients. In a November 2022 survey of 300 members of the American Society of Clinical Oncology (which advocates for prior-authorization reform), 96% of respondents reported that their patients' treatment had been delayed because of prior-authorization requirements. Other surveys of clinicians have had similar findings. Prior-authorization policies are also common. For example, a recent study found that more than 90% of Part D plans required prior authorization for the use of biologics in the management of psoriasis and psoriatic arthritis.[2] Clinicians may not know whether a prescribed drug will require prior authorization until after the prescription has been rejected by the pharmacy, which leads to frustration among prescribers and patients and delays in care.

To address these concerns, there have been efforts to accelerate the use of electronic prior authorization for prescription drugs. In 2018, Congress passed the SUPPORT (Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and

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Communities) Act, which included a section requiring Part D plan sponsors to support electronic prescribing systems that allow for the secure electronic transmission of prior authorization requests and responses between prescribers and the plan sponsor. Ultimately, enforcement of this section was delayed until 2022. Furthermore, since Congress did not require that *prescribers* use these systems, adoption of electronic prior authorization for prescription drugs in Part D is still not widespread today.

Recently, electronic real-time prescription-benefit tools have been implemented as part of additional attempts to support and streamline electronic prior authorization. Such tools are integrated into electronic health records (EHRs) and use formulary and insurance-benefits information to automatically display the patient's out-of-pocket costs for each prescription at the time of electronic prescribing. Versions of prescription-benefit tools that are used today are limited in two important and instructive ways, however. First, they lack interoperability — the vendors of such tools may not have drug-benefit information for all patients in a particular health system, and therefore the tool may work (i.e., display out-of-pocket drug costs and formulary status) for only a subgroup of a clinician's patients. Second, most of these tools don't yet include a streamlined, functional electronic prior-authorization system. When access to an electronic prior-authorization system is available, the system may require a separate account (and log-in) outside the EHR, which adds a potentially cumbersome step for clinicians.

A solution to these inefficiencies in the outpatient prescription-drug prior-authorization process would be a universal electronic prior-authorization system. Although such a solution may not be feasible in the near term, it's worth considering what it might look like. To have the greatest effect, such a system would need to apply to all universally to all payers, be fully electronic, display information in real time, and be available at no additional cost to clinicians and health systems (see table).

An ideal electronic prior-authorization system would be universal, meaning that it wouldn't be restricted to a single payer or type of payer; it should work for patients covered by Medicare, commercial insurance plans, and Medicaid. If an interoperable system for all commercial payers and state Medicaid programs cannot be developed, stakeholders could at least move toward the goal of establishing a single, standardized electronic prior-authorization form for prescription drugs. Nonelectronic versions of these forms already exist in more than 10 states. For example, the Massachusetts Health Care Administrative Simplification Collaborative has introduced standard prior-authorization forms for medical services and prescription drugs, which are accepted by state regulated health insurers . Developing a form that works for all Medicare plans or Medicaid programs or within certain geographic regions would be an important step toward a universal system.

The ideal system would also be fully electronic and seamlessly integrated with existing EHRs; a prescriber shouldn't need to log on to a proprietary third-party tool outside the EHR. Such a system would obviate the need to fax paper forms or trade phone calls. EHR integration would also enable the system to automatically populate clinical-information fields that may be required as part of a prior-authorization request (e.g., with information on the most recent ejection fraction in a patient with heart failure). The Department of Veterans

Affairs system is an exemplar in this area, illustrating how EHR integration can eliminate the need for multiple log-ins, faxes, and impersonal communications.[3]

Such a system should operate in real time. Like existing real-time drug-benefit tools, a universal electronic prior-authorization system should be able to provide patient-specific formulary and benefits information and notify the prescriber that a prior authorization is needed while the patient is still in the exam room. The system should also allow prescribers to complete a prior-authorization request electronically before a prescription is sent to the pharmacy.

Finally, to promote uptake, such a system would ideally be available at no additional cost to prescribers or health systems, as is currently the case for many real-time drug-benefit tools. Health plans and government payers could conceivably pay for such a system in part using the savings they would realize from reductions in the administrative effort needed to process (nonelectronic) prior-authorization requests, although evidence on savings associated with electronic prior authorization is limited. Similarly, some clinical practices may realize net savings from reducing staff time spent creating and managing prior-authorization requests.

Efforts to implement a universal system for prior authorizations would face many practical challenges. For example, the process of developing electronic standards can be technically complex (in part because it can require common terminology or classifications) and involve many stakeholders. To be most successful, standardization efforts should involve all organizations that participate in electronic-prescription transactions, including prescribers, retail pharmacies, health plans, electronic prescribing vendors, and organizations that administer pharmacy benefits. Furthermore, the mere fact that a system can be developed doesn't mean that it will work as intended. A study of an early version of an electronic prior-authorization system showed that it had a limited effect on medication adherence.[4] Another tool developed by the trade group America's Health Insurance Plans reduced the time between a prior-authorization request and a decision from about 19 hours to about 6 hours, with a large proportion of clinicians still reporting the need to use manual interventions (e.g., phone calls and faxes) to complete some prior authorizations.[5] As was seen during the implementation of EHRs, many iterations and tweaks will be necessary before there is widespread adoption of electronic prior authorization.

Prior authorization for prescription drugs may prevent the use of low-value services and, in some cases, improve patient safety. But existing prior-authorization processes are burdensome for clinicians and may delay patients' access to evidence-based pharmacotherapies. Electronic prior authorization will undoubtedly be part of Medicare Part D's future. Even though implementing a universal electronic prior-authorization system may be an overly ambitious or idealistic goal today, it is worth pursuing and this idealized system could serve as a framework for stakeholders moving forward. At minimum, such a system should be attainable within Medicare Part D.

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Characteristics, Benefits, and Potential Challenges associated with a Universal Electronic Prior-Authorization System for Prescription Drugs.*

Characteristic	Description	Benefits	Challenges and Barriers
Universal	The system would work for patients covered by Medicare (including various Part D plans), commercial insurance, and Medicaid	Would reduce clinician administrative burden as compared with having to use a different prior-authorization system for each payer or health plan	It might be difficult for individual health plans to standardize electronic forms or legacy prior-authorization systems
Fully electronic	The system would process all prior-authorization requests electronically, using the existing EHR; prescribers wouldn't need to log on to a proprietary third-party system outside the EHR	Prior-authorization requests could be automatically populated with clinical information from the EHR, thereby avoiding the need for faxes or separate log-ins	Vendors that provide electronic prior-authorization services might not have direct access to the EHR or the ability to modify it
Real-time availability	The system would be able to provide patient-specific formulary and benefits information and notify the prescriber that a prior authorization was needed while the patient was in the exam room; it would also allow prescribers to complete the prior-authorization request electronically before a prescription was sent to the pharmacy	The patient and prescriber would know immediately when a prescription required a prior authorization	Benefits information would have to be entered into the system correctly before the patient encounter, otherwise the system wouldn't be able to provide correct formulary information relevant to the prior-authorization request
No additional cost	The system would be available at no additional cost to prescribers or health systems	No-cost services tend to be adopted faster than services that require investment	Might result in "steerage" of prescriptions to certain pharmacies (e.g., if the electronic prior-authorization system is paid for wholly by an intermediary such as a pharmacy benefits manager – the system may default new prescriptions or refills to be sent to a mail-order pharmacy that is owned by the same company)

*EHR denotes electronic health record.