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PUBLIC INTEREST COMMENT

SIMPLICITY, INTEROPERABILITY, SYMMETRY, AND PRIVACY ARE ALL IMPORTANT GOALS FOR NEW HEALTHCARE INFORMATION RULES

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Medicaid Program; Patient Protection and Affordable Care Act; Reducing Provider and Patient Burden by Improving Prior Authorization Processes, and Promoting Patients' Electronic Access to Health Information for Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, and Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges; Health Information Technology Standards and Implementation Specifications
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We are pleased to comment on the Centers for Medicare and Medicaid Services (CMS) request for information on the proposed new rule to address prior authorization and reduce any burden on patients and providers.[1] The Mercatus Center at George Mason University is dedicated to advancing knowledge relevant to current policy debates. Toward this end, its scholars conduct independent, nonpartisan analyses of agencies' rules and proposals. With that in mind, this

1. Medicaid Program; Patient Protection and Affordable Care Act; Reducing Provider and Patient Burden by Improving Prior Authorization Processes, and Promoting Patients' Electronic Access to Health Information for Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, and Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges; Health Information Technology Standards and Implementation Specifications (proposed December 2, 2020) (to be codified at 42 C.F.R. pts 431, 435, 438, 440, and 457; 45 C.F.R. pts 156 and 170).

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comment does not represent the views of any particular affected party or special interest group. The authors of this comment include one health economist and two practicing physicians.

In general, we view the proposed rule as a positive development. We commend CMS for this action. Our comment has four main points:

1. The proposed rule will reduce reporting requirements, but more can be done to simplify billing reporting, such as, specifically, anticipating developments in data input such as natural language processing.
2. Electronic health record (EHR) interoperability is paramount, and the universal adoption of a standard, such as the Fast Healthcare Interoperability Resources (FHIR), is central to this task. The proposed rule is consistent with standardization, and we merely stress the importance of encouraging open and flexible EHR designs to accommodate future developments of data input and output.
3. In adopting the FHIR standard, mandates for the use of application programming interfaces (APIs) should the same for payers and providers or at least allow payers to adopt the standard at the same pace as the providers do.
4. The addition of "social risk data" seems important but also raises concerns over patient privacy that must be addressed adequately.

SIMPLIFYING BILLING REPORTING REQUIREMENTS

Implicit in the proposed rule is a recognition that EHRs will be (and ought to be) critical for patient care, along with a recognition that present-day EHRs are not doing the job they ought to. (The three of us have coauthored one other related public interest comment on that topic.[2]) Also, the proposed rule recognizes the need to make the process of prior authorization of reimbursable expenses faster and more predictable, and it recognizes the tightly integrated relationship between EHRs and prior authorization. We accept these assumptions.

Although we praise the bulk of the proposed rule, we urge CMS to err on the side of flexibility and adaptability. We urge CMS not to amplify the rigidity of present-day EHRs and not to hamstring the prior authorization process with excessive specificity. For a positive example in this direction, CMS is in the process of simplifying billing through changes to 2021 evaluation and management coding requirements.[3] Previously, CMS had imposed specific requirements for billing, such that doctors must report the exact number of organ systems examined to justify charges according to a pay scale. This requirement has led to what is often called "note bloat" to satisfy CMS reporting requirements. (Note bloat is the tendency of providers to copy and paste old records into a new EHR, resulting in duplicate information and a larger volume of text to sort through to find the desired clinical information.) Under the proposed rule, doctors need only document the total time spent in their encounters or the level of difficulty in their assessments and plans.

2. Robert F. Graboyes, Darcy Nikol Bryan, and Lyle Berkowitz, "Technical Expert Panel on Electronic Health Record Data Quality Best Practices for Increased Scientific Acceptability" (Public Interest Comment, Mercatus Center at George Mason University, Arlington, VA, October 30, 2020).
3. Some anticipated changes are described here: Andis Robeznieks, "How 2021 E/M Coding Changes Will Reshape the Physician Note," American Medical Association, November 6, 2020, https://www.ama-assn.org/practice-management/cpt/how-2021-em-coding-changes-will-reshape-physician-note.

It is also important that EHRs and prior authorization processes be sufficiently flexible and adaptable to dovetail with future developments in remote monitoring, artificial intelligence, and machine learning. To fulfill their maximum potential, future EHRs will have to incorporate data in currently unknown formats.

ENHANCE CLINICAL VALUE OF ELECTRONIC HEALTH RECORDS

We are particularly pleased that the proposed rule recognizes that EHRs will be essential to healthcare in coming years. A reliable, easily accessible, and easily readable record of an individual patient's health history will streamline providers' search for information on a given patient and the ability to analyze that patient's needs in the context of large-scale population data.

Present-day EHRs are far from ideal, in large part owing to their well-documented issues with decreasing provider efficiency.[4] The quest to record detailed billable activity has led to note bloat and has added little value. There is considerable opportunity to decrease these inefficiencies, thereby improving the clinical value of EHRs. Thus, we strongly agree with CMS's aspirations stated in its press release and in the proposed rule.[5] In our earlier public interest comment, we write, "today's EHRs are primarily designed to support billing and record keeping and only secondarily designed for patient care."[6] There is widespread perception among providers that today's EHRs hinder their work more than they help.[7] They divert the time of physicians and other providers toward bookkeeping rather than patient care. EHRs contain highly valuable information that is hard to aggregate and transfer across different platforms, thus diminishing their value.

THE GOAL OF INTEROPERABILITY

Interoperability—a seamless flow of data from one EHR to another—has represented the Holy Grail for healthcare professionals. And thus far, the quest for interoperability has largely failed, as different systems cannot talk to one another as easily as they should.[8] Perhaps the most glaring indicator of this failure is the ubiquitous use of fax machines—devices that had become obsolete by the end of the 20th century—to transfer information between institutions. Under the proposed rule, payers in Medicaid, the Children's Health Insurance Program (CHIP), and Qualified Health Plans (QHPs) would have to construct APIs to facilitate the exchange of data and prior authorization. APIs would have to meet the FHIR standard. According to CMS, "The FHIR standard is an innovative technology solution that helps bridge the gaps between systems so both systems can understand and use the data they exchange."[9]

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4. Kate Monica, "61% of Physicians Say EHR Systems Reduce Clinical Efficiency," *EHR Intelligence*, October 2, 2018; Michael Weiner, "Forced Inefficiencies of the Electronic Health Record," *Journal of General Internal Medicine* 34 (2019): 2299–2301; Christine Sinsky et al., " Allocation of Physician Time in Ambulatory Practice: A Time and Motion Study in 4 Specialties," *Annals of Internal Medicine* 165, no. 11 (2016): 753–60; Mindy E. Flanagan et al., "The Thrill Is Gone: Burdensome Electronic Documentation Takes Its Toll on Physicians' Time and Attention," *Journal of General Internal Medicine* 34, no. 7 (2019): 1096–7.
5. Centers for Medicare and Medicaid Services, "CMS Proposes New Rules to Address Prior Authorization and Reduce Burden on Patients and Providers," press release, December 10, 2020, https://www.cms.gov/newsroom/press-releases/cms-proposes-new-rules-address-prior-authorization-and-reduce-burden-patients-and-providers.
6. Graboyes, Bryan, and Berkowitz, "Technical Expert Panel."
7. Medical Economics Staff, "What's Ruining Medicine for Physicians: Difficulty Using EHRs," *Medical Economics* 95, no. 24 (2018): 50–60.
8. Linda Girgis, "5 Ways Interoperability Fails Physicians," *Physicians Practice*, May 30, 2019.
9. Centers for Medicare and Medicaid Services, "CMS Proposes New Rules."

Systems should be flexible enough to incorporate future, not-yet-imagined types of healthcare data. In particular, it's likely that future providers will increasingly enter clinical data into EHRs via natural language processing (NLP), as opposed to standardized box checking, and may extract clinical data similarly. Excessively specific data requirements and formats could impede the development of alternative inputs and outputs. We see no obvious dangers in the proposed rule and merely suggest that this potential conflict be kept in mind. In a paper published by the National Institutes of Health, Na Hong and coauthors explore the challenge of integrating NLP-generated data and standardized,[10] structured-query data into EHRs under the FHIR configuration. They investigate "whether the standardization process causes a loss in performance," and their results show that NLP and structured data entry could coexist in the FHIR framework.

Short of a mandate that Medicare Advantage plans meet the FHIR standard, we recommend minimizing any obstacles for meeting the standard voluntarily. The same holds true for other plans not included under the proposed rule. A patient history that incorporates only periods when the patient participated in Medicaid, Medicare, CHIP, or QHPs is not a complete patient history, after all. The proposed rule acknowledges this: "Neither the provisions in the CMS Interoperability and Patient Access final rule nor the proposed provisions here would preclude any payer from implementing these proposed policies regardless of whether the payer is directly impacted by the rule. We believe aligning these policies across all payers would benefit all payers alike."[11]

PRIOR AUTHORIZATION

Currently, prior authorization is a highly labor-intensive, time-consuming, often-arbitrary endeavor—in part owing to the irrelevant data offered by today's EHRs.

As CMS Administrator Seema Verma said in her blogpost on the proposed rule, "Prior authorization processes can drain significant time from the very purpose of medicine – caring for patients – in favor of often mindless nitpicking and wrangling with distant bureaucracies. The interminable delays and back-and-forth make prior authorization the top cause of physician burnout. These processes can delay needed care for patients who will sometimes unnecessarily pay out of pocket or even forgo important care just to avoid the inevitable slog."[12]

Admirably, the proposed rule seeks to expedite the process. The rule proposes "a maximum of 72 hours for payers, with the exception of QHP issuers on the FFEs, to issue decisions on urgent requests and seven calendar days for non-urgent requests."[13]

For the most part, such time frames seem reasonable. Two caveats come to mind, though. First, some modest percentage of prior authorizations may legitimately take longer than 72 hours, so it might be wise to build in the capacity for a limited number of penalty-free exceptions. Second,

10. Na Hong et al., "Developing a Scalable FHIR-Based Clinical Data Normalization Pipeline for Standardizing and Integrating Unstructured and Structured Electronic Health Record Data," *JAMIA* 2, no. 4 (2019): 570–79.
11. Medicaid Program; Patient Protection and Affordable Care Act; Reducing Provider and Patient Burden by Improving Prior Authorization Processes, and Promoting Patients' Electronic Access to Health Information for Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, and Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges; Health Information Technology Standards and Implementation Specifications (proposed December 2, 2020) (to be codified at 42 C.F.R. pts 431, 435, 438, 440, and 457; 45 C.F.R. pts 156 and 170).
12. Seema Verma, "Reducing Provider and Patient Burden, and Promoting Patients' Electronic Access to Health Information," *Centers for Medicare and Medicaid Services* (blog), December 10, 2020.
13. Centers for Medicare and Medicaid Services, "CMS Proposes New Rules."

the expedited prior authorization is likely dependent upon improved EHRs, and arbitrary time limits without adequate infrastructure can lead to perverse incentives. For example, the United Kingdom established a maximum four-hour wait time for emergency rooms, but resources were inadequate to meet emergency room demand. What ensued was gamesmanship—for example, patients wait for extended periods in ambulances because the four-hour clock does not actually begin until the patient passes through the emergency department doors. In addition to causing providers to fail the four-hour test in a de facto sense, this lack of infrastructure has led to excessive demand for ambulance time.[14] CMS would do well to contemplate how insurers might respond to infeasible time demands and how perverse incentives might be minimized.

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The CMS announcement says of the potential advantages of improved EHR–prior authorization interaction, "If just a quarter of providers took advantage of the new electronic solutions that this proposal would make available, the proposed rule would save between 1 and 5 billion dollars over the next ten years." In a healthcare system currently spending $3.8 trillion per year, such savings are a mere drop in the bucket. (Using these figures, savings would amount to no more than around 0.01 percent of total healthcare spending.) But that seemingly small number doesn't particularly bother us. First, we suspect that those numbers do not fully capture the full benefits that success would entail. We suspect, for example, that the $1 billion to $5 billion figure does not capture improved health of patients, psychic well-being of patients and providers, and better population data for improving the standards of care. Second, we also suspect that savings to the US healthcare system will likely come in the form of many, many drops in the bucket, rather than one-shot deals.

Another small but worthy goal in the proposed rule is that of reducing the use of fax technology. The healthcare industry is one of the last holdouts of this now-antiquated technology. Continued use of fax machines should be considered prima facie evidence of failure.[15]

The proposed rule would make the API standards mandatory for payers, but voluntary for providers. This condition raises the possibility of private insurers investing heavily in information systems that are scarcely used by providers.[16] Our colleague Elise Amez-Droz has speculated that the new standards will place small providers at a competitive disadvantage against large, well-capitalized providers.[17] These questions are worthy of consideration. Perhaps API mandates on private payers could be made contingent upon sufficient buy-in by providers.

Finally, the proposed rule seeks to incorporate "social risk data" in patient histories: "We recognize that social risk factors (e.g., housing instability, food insecurity) influence patient health and health care utilization. And, we understand that providers in value-based arrangements rely on comprehensive, high-quality social risk data." This aspiration cuts two ways. First, healthcare usage explains a little over one-tenth of the variation in health status across the population.

14. Ronald Bailey, "Queue Up," *Reason*, June 2008.
15. Miriam Reisman, "EHRs: The Challenge of Making Electronic Data Usable and Interoperable," *P&T* 42, no. 9 (2017): 572–75.
16. Medicaid Program; Patient Protection and Affordable Care Act; Reducing Provider and Patient Burden by Improving Prior Authorization Processes, and Promoting Patients' Electronic Access to Health Information for Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, and Issuers of Qualified Health Plans on the Federally-facilitated Exchanges; Health Information Technology Standards and Implementation Specifications (proposed December 2, 2020) (to be codified at 42 C.F.R. pts 431, 435, 438, 440, and 457; 45 C.F.R. pts 156 and 170), 275.
17. Elise Amez-Droz, personal communication to authors, December 29, 2020.

Therefore, it is not the only determining factor of health.[18] And second, the inclusion of social risk data raises some concerns over patient privacy that must be addressed adequately.

In conclusion, we strongly commend CMS for its proposed rule and merely suggest a few areas for further study.

18. Edwin Choi and Juhan Sonin, "Determinants of Health," *GoInvo*, April 14, 2020.