



June 3, 2019

VIA ELECTRONIC SUBMISSION

Centers for Medicare & Medicaid Services

Department of Health and Human Services

Attention: CMS-9115-P, Mail Stop C4-26-05

7500 Security Boulevard

Baltimore, MD 21244-1850

Re: CMS-9115-P; Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans in the Federally-Facilitated Exchanges and Health Care Providers

Dear Administrator Verma:

The Medicare Rights Center (Medicare Rights) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) proposed **Interoperability and Patient Access** rule.

Medicare Rights is a national, nonprofit organization that works to ensure access to affordable health care for older adults and people with disabilities through counseling and advocacy, educational programs, and public policy initiatives. Medicare Rights provides services and resources to three million people with Medicare, family caregivers, and professionals each year.

The following comments are informed by our experience assisting people as they navigate the Medicare program.

General Comments

The US health system can be a confusing muddle, even for experienced navigators. One problem that arises again and again is the reliance on patients to provide their complete health information to their providers, an expectation that cannot reasonably be met when a patient has a long history of tests, diagnoses, treatments, interventions, referrals, hospitalizations, and prescriptions. Currently, few people can easily access their complete health information in interoperable forms, denying them the opportunity to simply sign a form or press a button and have their providers supplied with all of the pertinent information for their condition and care.

This is not only inefficient but can be harmful. The incomplete picture many consumers are able to draw of their health histories might leave out vital information. This could lead to delays in treatment or exacerbation of conditions.

We agree with the rule's principle that "every American should be able, without special effort or advanced technical skills, to see, obtain, and use all electronically available information that is relevant to their health, care, and choices – of plans, providers, and specific treatment options."¹ Improving interoperability and consumer access to their personal health information as well as public information has the potential to improve care, coverage decisions, and health outcomes; reduce uncertainty and waste; and give consumers more confidence in their health care decisions and the decisions of their providers. This does not mean, however, that we should expect consumers to use their new access to become perfectly adroit in navigating the health care system or shop their way to savings. The amount of shopping and savings we can realistically expect is very small and should never be the impetus for significant systemic change. Most people do not manage their health, care, or costs independently. They make decisions about treatments and choices about coverage options in partnership with their providers and family caregivers.

Nor should we create heavy new obligations and burdens on consumers to direct data exchanges from place to place. Players within the health system must be responsible for designing systems to identify where information should be shared, seek necessary permissions, and shepherd the information from entity to entity, rather than waiting for overburdened consumers, families, and caregivers to spontaneously request it and deliver it to the appropriate destination.

Finally, we must never overlook the real privacy concerns created by increased data sharing and must prohibit the information from being used in any way counter to the consumer's wishes. Preserving the safety, privacy and trust of beneficiaries using mobile devices to access, use and direct their health information must be at the forefront of every regulatory decision in this space. The Administration must do more to protect people's privacy and prepare them for this fundamental transformation in health information exchange and protection. This is an opportunity for deep education that will benefit consumers for years to come.

Open API Proposal for MA, Medicaid, CHIP and QHP Issuers in FFEs

CMS proposes to require that Medicare Advantage (MA) organizations and other payers—Medicaid state agencies, Medicaid managed care plans, CHIP agencies, CHIP managed care entities, and QHPs in FFEs—make a variety of data accessible to consumers through the adoption and implementation of "open" Application Programming Interfaces (APIs). This would ensure that MA enrollees, Medicaid beneficiaries, CHIP enrollees, and enrollees in QHPs in FFEs would be able to use the application of their choice to access and use their own electronic health information, claims data, and other information relevant to managing their health. We support this proposal. Health plans have a unique perspective on a patient's medical encounters, helping provide a more complete picture of a patient's health history. Furthermore, a robust system built on APIs will let consumers choose from a range of applications that pull in health data from various health care providers and hospitals, helping form a comprehensive picture of their health and health care and facilitate information sharing.

That said, claims data are generated for administrative/billing purposes and will not fully meet beneficiaries' information needs. People will need education and context for the data they will be receiving. For example, a claim may show that a given test was performed but not show results or interpretations of the test. Importantly, the extent to which disease severity, risk factors, or prognosis can

¹ 84 FR 7619.

be assessed using claims is extremely limited. This makes it imperative that plans set clear expectations about the kind of information patients should expect to receive. It also demonstrates that such data are likely more valuable for provider use rather than patient or caregiver use.

CMS proposes to require API use by these entities to be “pro-competitive.” This would include proactively advising enrollees they are not required to use only the organization’s own or preferred applications to access, use, and share their health information. It would also include information relevant to the enrollee about how they could request access to their information through a third-party application of their choosing. We support these requirements. Consumers must not be locked in to use of specific applications but must have the freedom to choose those that best fits their needs. Ideally, this will result in consumers having only one application they must maintain rather than multiples, even in their insurance or providers change.

CMS explicitly is not proposing to require that organizations subject to this proposed rule offer patients or providers the ability through the API to write information directly to patient records held by the organization. While we understand the limitations of current technology, we urge CMS to continue to promote the bi-directional flow of information. We should be encouraging patients and family caregivers to use online access, communicate electronically with providers, and contribute information to their medical record that is specific and material to their care. Patients must be able to correct, update, or challenge the information shared with them to ensure that it captures their history, goals, preferences, social determinants of health, and any other relevant information. The absence of this functionality curtails the potential of electronic health records.

CMS proposes to require plans to make provider directory data, network information, drug benefit data, pharmacy directory information, and formulary or preferred drug list data available on the APIs as well. We strongly support requirements that would enhance beneficiary access to these data, though we caution that existing rules requiring such information lacks the necessary oversight and enforcement to spur plans to offer complete and accurate information and that provider directories, for example, are notoriously error ridden. Without a guarantee of accuracy, such information may be worse than no information at all. More must be done to ensure that all of the network and provider information plans promulgate, through any format or portal, is accurate and complete. As CMS notes,² access to a comprehensive provider directory could help consumers choose health plans, but this functionality is utterly destroyed if the directories are not accurate and up-to-date.

We appreciate CMS reiterating that covered entities will retain duties under HIPAA and other law to protect the privacy and security of the information the entity holds and that it must take reasonable steps to ensure an individual’s information is only disclosed as permitted or required by applicable law. However, we have seen examples of entities using HIPAA in the past as a shield to excuse failures to disclose. We hope CMS will do yet more to make clear the requirements HIPAA places on entities to share information with consumers and their chosen caregivers.

The proposal makes clear that covered entities are not responsible under the HIPAA Rules for the security of PHI once it has been received by a third-party application chosen by an individual but should make information available to beneficiaries about how to select a safe application, how to safeguard their data, and how to submit complaints. In particular, we applaud the recommendation that resources must be made available in non-technical, consumer-friendly language.

But educational resources are not enough to promote privacy and security. The health technology landscape has evolved greatly in the last few years; we now have a much-expanded universe of

² 84 FR 7639.

smartphone and mobile apps, remote monitoring devices, wearables and other consumer-facing apps that help to collect, send, manage and use one's health data. Regrettably, federal laws governing portability and privacy have not kept up.

As CMS continues to encourage open APIs to facilitate the exchange of information with consumer-facing, third-party apps, the Administration must do more to protect consumers' privacy or risk significant erosion in public trust and confidence in electronic health information exchange. In particular, we are concerned that CMS expects consumers "to exercise due diligence on their own behalf in reviewing the terms of service and other information about the applications they consider selecting."³ This expectation of due diligence must not be allowed to excuse a cavalier approach to consumer privacy breaches or a failure to warn about dangers.

We strongly encourage CMS to explore additional options to help consumers guard their information and their privacy. For example, CMS could encourage the use of ONC's Model Privacy Notice (MPN), which uses a digestible format and plain language to disclose how apps use, share and protect the privacy and security of health information. The MPN is designed to help consumers make clear comparisons about different apps' data sharing policies and truly informed decisions when selecting apps.

Gaps in the current health data regulatory patchwork mean that much of the information currently being generated and used in health care (e.g., patient-generated data, personally identifiable data, "big data") do not have robust privacy and security protections. Indeed, the same data might or might not be subject to HIPAA's privacy and security protections depending upon whether it was created or is currently stored by a covered entity or an individual patient. As new technologies continue to develop and proliferate, they will produce new data without a clear framework governing who controls it, who has access to it, who is responsible for protecting it and whether it will be able to interact with the rest of the health care system. There is an urgent need for a more expansive conversation about how to responsibly and ethically collect, use and share data for health. And this conversation must be ongoing, drawing on the expertise of consumers and consumer advocates as well as data and health care professionals. We are eager to work with CMS and the Administration more broadly to consider how best to promote the dual goals of access to information and privacy.

CMS also proposes to require MA organizations to make standardized data concerning adjudicated Part D claims, including remittances and enrollee cost sharing, available through the API to enrollees covered under a MA-PD plan within 1 business day after a claim is adjudicated. This includes information from a pharmacy benefit manager if the plan engages one. We support making these data available to consumers and their chosen providers in order to help ease problems accessing affordable medications and navigating the flawed Part D appeals process.

CMS seeks comment on requirements for patient notice and consent to allow providers to access data transfers directly from payers. We urge CMS to consult with consumers, caregivers, and advocates to ensure that any notice and consent opportunities would be comprehensive, understandable, and not burdensome for patients. This should include testing of language, delivery, duration, and timing of any notices and requests for consent.

Health Information Exchange and Coordination Across Payers: Establishing a Coordination of Care Transaction to Communicate Between Plans

CMS proposes to give beneficiaries the ability to direct a limited data set between health plans up to five years after enrollment has ended. We agree this could enhance plans' ability to provide coordinated, high-

³ 84 FR 7622.

quality care and reduce administrative burdens for consumers. It is important that the Administration ensure continued enforcement of necessary and appropriate consumer protections and anti-discrimination policies that prevent this information from being used as the basis to deny or delay coverage, increase rates or otherwise limit consumers' access to care. Additionally, CMS should specify limitations on data exchange for certain types of information that are protected by federal, state or local law.

Finally, we encourage CMS to consider how to ensure these requests to share data are truly upon informed enrollee request, and without coercion or improper inducement. For example, we do not support allowing plans to offer gift cards or other such "reward" inducements to beneficiaries to encourage them to share their data.

Improving the Medicare-Medicaid Dually Eligible Experience by Increasing the Frequency of Federal-State Data Exchanges

CMS proposes to require all states to participate in buy-in data exchanges with CMS on a daily basis. We support this proposal. Though over half of states currently use daily exchanges, that leaves many states more infrequently exchanging data. Daily submissions, and the ability to for states to receive daily response files from CMS, spread state staff workload more evenly across the month, permit errors to be corrected more quickly, and connect new beneficiaries more quickly to Medicare benefits.

Similarly, CMS proposes to require all states to participate in "MMA" data exchanges on a daily basis. We support this proposal which will help speed auto-enrollment of full-benefit dually eligible beneficiaries into Medicare prescription drug plans and deeming full- and partial-benefit dually eligible beneficiaries automatically eligible for the Medicare Part D Low Income Subsidy.

Information Blocking and Public Reporting

CMS proposes to use public-facing websites such as Physician Compare to identify providers, clinicians, and hospitals who may be engaging in information blocking. We support this proposal. Deliberate efforts to restrict information sharing for competitive or financial reasons ("information blocking") should not be tolerated, and we support efforts to provide consumers more information about whether their clinicians and hospitals are engaging in these practices. We caution that allowing a non-response to leave the field blank on the website might encourage providers to fail to respond rather than respond negatively.

We also appreciate CMS's intention to determine how to best display and meaningfully communicate the indicator on the Physician Compare website, including the exact wording, after user testing and stakeholder feedback. We also encourage CMS to develop a mechanism to collect feedback from consumers on information blocking related to health data through consumer-facing applications.

Revisions to the Conditions of Participation for Hospitals and Critical Access Hospitals

CMS proposes to expand requirements for interoperability within the hospital and Critical Access Hospital Conditions of Participation by requiring electronic patient event notifications. This would require hospitals to convey at least the patient's basic personal or demographic information, the name of the sending institution, and the diagnosis, when permissible. We support this requirement. In our response to the IPPS/LTCH proposed rule from late 2018 (CMS-1694-P), we cautioned that revising Conditions of Participation related to interoperability as a way to increase electronic sharing of data by hospitals could potentially put access to care at risk, especially if facilities were not previously eligible for incentives to adopt electronic health records (EHR). We are relieved, therefore, that this proposal would apply only to facilities that have already moved into the EHR space.

Despite our cautions, we agree that tying information sharing to Conditions of Participation could be a tremendous benefit to millions of Medicare patients across the country, helping to ensure information exchange when patients are transitioning from the hospital to home (or another care environment), thereby improving care coordination and patient safety. We encourage CMS to expand the patient population to whom this requirement applies to include patients who present in the ER, including those who are admitted in observational status. Planning for a safe care transition begins when a patient presents in the ER, regardless of whether they are admitted to the facility. In addition, notifying the community practitioner when a patient visits the ER enables them to intervene immediately, which can improve outcomes for the patient and result in better and more efficient coordination of care.

Request for Information on Advancing Interoperability Across the Care Continuum

We strongly support CMS's efforts to increase information sharing around transitions of care. Transitions are a point of particular vulnerability for consumers and the risk of miscommunication, missing instructions, or other errors requires especial efforts to mitigate any unintended consequences. As with all such endeavors, we urge CMS to engage with beneficiaries and caregivers to ensure that their needs and pain points are identified.

Conclusion

Thank you for this opportunity to comment. For additional information, please contact Lindsey Copeland, Federal Policy Director at LCopeland@medicarerights.org or 202-637-0961 and Julie Carter, Senior Federal Policy Associate at JCarter@medicarerights.org or 202-637-0962.

Sincerely,



Fred Riccardi

President

Medicare Rights Center