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September 27, 2019

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8016
Baltimore, MD 21244-8016

RE: CMS- 1715-P: CY 2020 Revisions to Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; etc.

Dear Administrator Verma:

Thank you for soliciting feedback on the Centers for Medicare & Medicaid Services' (CMS') proposed regulations updating the Physician Fee Schedule (PFS), including the Merit-based Incentive Payment System (MIPS). Provisions in these regulations—along with policies that CMS could implement in response to the agency's requests for information (RFIs)—can further advance the quality and coordination of care for patients by improving treatment for patients with substance use disorder, increasing the transparency of the financial relationships between clinicians and medical device manufacturers, and enhancing the interoperability and safety of electronic health records (EHRs).

The Pew Charitable Trusts is a non-profit research and policy organization with several initiatives focused on improving the quality and safety of patient care, facilitating the development of new medical products, and enhancing the coordination of care. Pew's health information technology initiative focuses on advancing the interoperable exchange of health data and improving the safe use of EHRs. Pew also develops and supports state and federal policies that expand access to effective treatment for substance use disorders (SUDs).

This rule makes updates to the PFS and other changes to Medicare Part B payment policies by:

- Adding Medicare enrollment of opioid treatment programs;
- Establishing bundled payments for substance use disorders;
- Requiring medical device companies to submit brand- and model-specific data to the Open Payments program; and
- Soliciting—through a series of RFIs—information on the interoperability and safe use of EHRs.

Payments for substance use disorder services will increase access to care

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Medication-assisted treatment (MAT), which pairs behavioral therapy, such as counseling, with U.S. Food and Drug Administration (FDA)-approved medications, is the most effective way to treat opioid use disorder (OUD). Unfortunately, only about 10 percent of individuals with substance use disorder received any kind of treatment in 2018. The Medicare population has a smaller but significant treatment gap. Fewer than 25 percent of the 974,000 individuals aged 65 and older with a substance use disorder received treatment.[1]

The SUPPORT Act made important advances in expanding the availability of MAT, including Section 2005, which establishes a new Medicare Part B benefit for services offered at Opioid Treatment Programs (OTPs). Pew is encouraged by CMS efforts to implement the benefits required by SUPPORT and other proposals that could advance access to MAT.

This proposed rule helps advance the availability and integration of OUD treatment services in three important ways:

1) Establishing Medicare payments for care coordination in office-based settings;
2) Establishing Medicare payments for services available at OTPs;
3) Soliciting feedback on Medicare payments for services in emergency departments.

Medicare payments for care coordination in office-based settings

CMS has proposed paying for care coordination as part of monthly bundled payments for Medicare beneficiaries receiving OUD treatment in office-based settings. In addition to care coordination, the bundle also includes treatment planning and counseling activities; CMS pays for medications and laboratory tests separately. CMS seeks comments on whether there should be a separately billable code or codes to describe additional resources involved in furnishing OUD treatment-related services after the first month, such as treatment plan revisions.

Office-based opioid treatment is outpatient treatment delivered outside OTPs and typically involves prescriptions for buprenorphine and naltrexone[2] in settings, including Federally Qualified Health Centers, and other primary care and psychiatry practices. Addiction medicine specialists can be involved in this type of treatment, but it often includes non-specializing physicians, nurse practitioners, and physician assistants.

Many parts of the country do not have access to office-based treatment. Nationwide, 44 percent of counties do not have a physician that is authorized to prescribe buprenorphine.[3] Sixty percent of rural counties lack any waivered provider.[4]

Care coordination is an essential part of office-based treatment. The Agency for Healthcare Research and Quality (AHRQ) defines care coordination as, "organizing patient care activities and sharing information among all of the participants concerned with a patient's care to achieve safer and more effective care."[5] Care coordination is particularly important for individuals with chronic conditions and those with more complex needs. Despite the recognition of substance use disorder

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(SUD) as a chronic medical condition that is highly co-morbid with other chronic diseases,[6] care coordination for individuals with SUDs generally lags behind coordination for other chronic conditions. For OUD patients, care coordination may involve activities related to medication management, psychosocial services and treatment of co-occurring conditions. The goal is to increase engagement and retention in treatment, manage co-morbid medical conditions, and successfully link medical and behavioral interventions.

In states that have successfully incorporated care coordination into treatment system reforms, the number of buprenorphine prescribers has increased and patient access to care has improved.[7] Evidence-based models typically involve payments for staff, such as social workers and nurses, who help support the prescriber's management of the patient.

One example of a state successfully using care coordination to support MAT prescribers is Vermont's "hub and spoke" system, which was implemented in 2014. Patients begin treatment in specialized settings, or hubs, which stabilize patients, and provide ongoing subject matter expertise and consultation to office-based providers functioning as spokes. Spokes are community-based prescribers supported by MAT care teams consisting of a registered nurse and behavioral health providers. Duties range from arranging urine testing, authorizing pharmacy refills, diversion control, crisis management and coordinated referrals between the spoke and hub. Patients have reported decreased opioid use and emergency department visits.[8] In addition, Vermont realized a 64 percent increase in physicians waivered to prescribe buprenorphine and a 50 percent increase in patients treated by a waivered physician.[9]

Successful state reforms ultimately depend upon a sustainable payment system. Many state Medicaid programs, such as those in Virginia and Massachusetts, have built such a system by reimbursing providers for care coordination and other elements of care. Adding Medicare payments for care coordination will provide additional incentives to providers to build out office-based treatment and provide a sustainable source of funding in a way that federal State Opioid Response grants do not.[10]

CMS' proposed Medicare payments for care coordination as part of the bundle payments for office-based treatment represent an opportunity to build on Medicaid reforms and provide long-term support for grant-funded reforms occurring at the state level. To ensure success, it is important to provide flexibility for office-based practices seeking to incorporate OUD treatment. As proposed, the bundles require individual therapy, group therapy and counseling, but this may not be feasible for practices that could otherwise benefit from care coordination services, particularly those in rural areas or with limited access to a counselor workforce. Further, counseling is one aspect of MAT, but patients may benefit from OUD medications without counseling. [11] Pew agrees with the assessment by CMS that "treatment for OUD can vary, and that MAT alone has demonstrated efficacy." However, existing evaluation and management codes may not adequately capture the activities necessary to prescribe OUD medications in office-based settings. Counseling should be covered and available, but requirements for the service should not be a barrier to medication access and coordinated care.

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Recommendation:

- CMS should review existing evaluation and management codes to ensure they adequately capture all the activities necessary to support prescribing OUD medications and coordinate care in office-based settings. If the existing codes are inadequate, CMS should establish Medicare payments for care coordination in all office-based settings, without requirements for counseling or other behavioral health services. Care coordination payments could encompass activities such as urine drug screens, crisis management, referrals to specialists and counselors, as needed, that are coordinated by support staff such as nurses, counselors or social workers. This change would reflect the reality that OUD treatment spans settings with and without onsite counseling, and includes situations where medication is prescribed but counseling is unavailable or undesired. Further, this change would support practices that would benefit from care coordination, but are unable to provide onsite counseling.

Medicare payments for services at Opioid Treatment Programs

CMS has proposed a series of bundled Medicare rates to pay for medication and non-medication services provided at OTPs. Pew applauds CMS for implementing this provision of the SUPPORT Act. Payment barriers, such as the lack of Medicaid coverage in some states and Medicare coverage nationwide, have contributed to a siloed system of care. In particular, many SUD treatment facilities do not accept insurance. In 2018, one-third of facilities did not accept Medicaid and nearly two-thirds did not accept Medicare.[12] Medicare payments to OTPs will help increase the number of treatment providers accepting this type of insurance and will advance access to these facilities in a meaningful way.

Pew supports the creation of multiple bundles that cover treatment scenarios for all types of MAT. Patients should have access to multiple medications to ensure they receive the treatment that is appropriate for them. OTPs are the only location where all three approved MAT medications can be made available, allowing patients and practitioners to choose the most appropriate treatment path. Payment options that allow for patients' various medication and psychosocial needs is critical in ensuring they receive appropriate care.

Establishing a $0 copay will minimize barriers to patient access to OUD treatment services, especially for low-income patients. In 2018, 38 percent of individuals with a substance use disorder were below 200 percent of the federal poverty level.[13]

Pew supports CMS' decision not to propose additional conditions on OTPs for participation in Medicare beyond existing SAMHSA certification and accreditation requirements. In addition to federal requirements, OTPs may face state and local regulation. Additional requirements for participation in Medicare could have become a barrier for OTPs.

The use of methadone to manage OUD is supported by decades of evidence in reducing illicit opioid use and mortality. OTPs are critical providers of MAT because they are the only facilities

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that dispense methadone for OUD. They also deliver other forms of MAT, counseling and other services. Patients receiving methadone must undergo supervised medication dosing, which generally occurs daily at the OTP. Therefore, these facilities are a hub of OUD treatment activity that should be coordinated with primary care providers.

Recommendations:

- CMS seeks comment on whether intake activities, which may include services such as an initial physical examination, initial assessments and preparation of a treatment plan, as well as periodic assessments, should be included in the definition of OUD treatment services. The SUPPORT Act did not specifically require coverage of intake activities, but federal regulations require initial and periodic assessments.[14] Therefore, CMS should use its implementation discretion to cover these services. Pew sees various paths CMS could take to implement coverage, such as including it in the proposed bundles or creating a new standalone bundle for treatment initiation. Pew recommends that CMS ensure that all services required by federal OTP regulations and SAMHSA guidelines are covered and adequately compensated.

- Additionally, CMS should review existing evaluation and management codes and consider paying for care coordination within OTPs. Twenty-two percent of Medicare beneficiaries have five or more chronic conditions.[15] Therefore, it is imperative that care received by other providers and specialists is coordinated. People with an SUD have a wide range of health conditions that are directly related to those disorders, such as cardiomyopathy, gastritis, and cirrhosis of the liver.[16] Like other chronic diseases, untreated SUDs can result in injury, disability, and death.[17] Coordinated care also would be in line with SAMHSA guidance, which recommends that OTP physicians treat co-occurring conditions directly and by coordination. "OTP physicians can prescribe medication as appropriate for co-occurring medical and psychiatric disorders. Program staff should provide care coordination, making referrals for medical and psychiatric treatment when indicated."[18]

  If CMS determines that the existing evaluation and management codes, such as codes for behavioral health integration services under the Psychiatric Collaborative Care Model, [19] are adequate for care coordination, the agency could allow OTPs to use them. Alternatively, CMS could add care coordination activities to the proposed OTP bundles.

Medicare payment for services provided in emergency departments

CMS seeks feedback on the use of MAT in the emergency department setting, including initiation of MAT and the potential for either referral or follow-up care, as well as the potential for administration of long-acting MAT agents in this setting. Pew encourages CMS to propose payments for OUD treatment initiation in emergency departments in future rulemakings.

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The national rate of overdose-related visits to emergency departments nearly doubled between 2005 and 2014.[20] Hospital-based care represents a critical opportunity to initiate treatment and connect people with OUD to care.[21] Patients who receive information about drug treatment in the hospital post-overdose are more likely to seek treatment.[22]

Recognizing the potential to initiate care in emergency rooms, federal regulations allow the administration of methadone and buprenorphine in emergency situations to treat withdrawal symptoms and arrange for treatment.[23] In these cases, methadone can be administered outside of an OTP and physicians do not need the waiver typically required to prescribe buprenorphine, though treatment can last no longer than three days.

Initiating MAT with buprenorphine in the emergency department produces better health outcomes[24] and is cost-effective[25] compared with other approaches. A randomized clinical trial showed that more patients were engaged in treatment 30 days after buprenorphine was initiated in the emergency department and coupled with a referral, compared to interventions that did not include buprenorphine.[26] Another study found that emergency department induction of buprenorphine was more cost-effective than either brief intervention or referral upon discharge.[27]

Emergency departments represent a critical opportunity to initiate care, but it is necessary to transition patients to long-term care for this chronic condition. States have implemented a variety of programs to connect patients to care from the emergency department to community-based providers:

- In Ohio, the Department of Mental Health and Addiction Services used a federal grant to fund emergency departments that implemented a model of care encouraging treatment initiation and the transition of patients from the hospital to intermediary primary care while they await specialized care at OTPs or office-based opioid treatment (OBOT). This redesign has allowed hospitals to hire primary care providers as case managers to transition patients.[28]

- Rhode Island's AnchorED program connects patients with a certified peer recovery specialist prior to discharge from the emergency department. Peer recovery specialists maintain follow-up with the patient for 10 days following release from the emergency department to aid in navigating the treatment system and support their recovery. More than 1,400 individuals met with a peer recovery coach in the emergency department through AnchorED during the first 29 months of the program and more than 80 percent of those individuals engaged in recovery support services upon discharge.[29] Peer recovery specialists are required as part of Rhode Island's Levels of Care for Emergency Departments and Hospitals, which also outline standards for diagnosing and treating OUD in these settings.[30]

- In 2015, New Jersey implemented the Opioid Overdose Recovery Program, a care coordination program modeled after AnchorED, to facilitate the entry of individuals who

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receive naloxone into SUD treatment. Of the 293 overdose patients admitted to emergency departments in five counties from January 2016 to June 2016, roughly 37 percent (109 patients) entered treatment. [31]

Recommendation:

- Pew encourages CMS to propose payments for OUD treatment initiation in emergency departments in future rulemakings.
- Additionally, CMS should consider payments for emergency department-specific activities to ensure referrals to long-term treatment and follow-up care after care begins. This includes paying for staff activities such as scheduling follow-up appointments after treatment initiation, and arranging access to supportive services.

Addition of device identifiers to Open Payments would add more transparency

The Open Payments program, which implements provisions of the Physician Payments Sunshine Act signed into law as section 6002 of the Patient Protection and Affordable Care Act, CMS gives the public easily accessible and understandable information about the financial relationships between medical product manufacturers and clinicians. The National Academy of Medicine—formerly called the Institute of Medicine—has said that these financial relationships "present the risk of undue influence on professional judgments and thereby may jeopardize the integrity of scientific investigations, the objectivity of medical education, the quality of patient care, and the public's trust in medicine."[32]

Through the Open Payments program, medical product manufacturers must report any transfers of value to clinicians, including fees associated with speaking engagements to discuss a particular drug or medical device. As part of those reports, manufacturers must also list the name of the product associated with the fee. In addition, for drugs, CMS requires the submission of national drug codes (NDCs), which indicate product-specific information, such as the brand and strength. CMS does not currently require the use of similar codes for medical devices.

However, the Department of Health and Human Services (HHS) Office of the Inspector General (OIG), in a report published last year, found that the submitted drug and device names are often invalid, and that the drug names often do not align with the submitted NDCs.[33] To address these problems, the HHS OIG recommended that CMS use FDA or other data to validate the submitted NDCs, and require more specific device information.

The addition of UDI data to the Open Payments program would meet those recommendations by making available more specific device data and enabling CMS to validate the information submitted against an FDA database that contains device identifiers. Specifically, CMS proposed adding the device identifier portion of UDI—which indicates the brand and model of product but lacks other aspects of the code, such as a manufacturing date.

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Adding these device identifiers to the Open Payments database will ensure that the availability of analogous information on medical technology and drugs. This information would allow consumers making medical decisions to better understand the financial relationships between clinicians treating them and device manufacturers.

Wider adoption of UDI, through claims, would amplify benefits

In the proposed rule, CMS indicates that the UDI system has become increasingly adopted, making it feasible to add device identifiers to the Open Payments database. As an example of this phenomenon, CMS points to regulations from the Office of the National Coordinator for Health Information Technology, which has required electronic health records be able to document the UDIs of implants used in care.

In this proposed rule, CMS rightly recognized that the more widespread use of the UDI system provides greater product-specific visibility. With that recognition, CMS should also take steps to provide product-specific transparency in another agency priority: the more effective use of health insurance claims data to improve patient care.

CMS has repeatedly emphasized the value of claims data

As part of recent rulemaking, CMS has advanced policies that would equip patients with data held by health plans, including claims information. Previously through the Blue Button 2.0 program, CMS ensured that patients can download their Medicare claims data. Now, via regulations proposed earlier this year, CMS proposed to extend that capability for patients with insurance coverage by private health plans, thus giving them a holistic understanding of the services and treatments that they have received from different health care providers.

Equipping patients with this information builds on previous efforts from CMS to leverage claims to enhance care, including by providing increased access to the data by researchers working to identify ways to improve care quality and reduce costs. For example, in prior policies CMS has underscored that the analysis of claims data can help identify opportunities to improve care quality and made Medicare Advantage, Children's Health Insurance Program, and Medicaid claims data available for researchers.[34]

Claims are especially useful for patients and researchers because, unlike other information sources, they contain data for nearly every encounter with the health care system for a specific individual. For example, claims information collected over many years may contain data showing that a patient received a specific prescription drug, had surgery, and visited the emergency department—all in different health care systems. Claims transmissions from health care providers to payers are already standardized, resulting in easier aggregation of information across the health care system. It is precisely this characteristic of claims that has made them a valuable source of information for researchers to evaluate quality and safety.

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CMS indicates that it has advanced these policies around claims data because of challenges in aggregating clinical data from EHRs. As CMS states in this proposed rule, "Whereas EHR data is frequently locked in closed, disparate health systems, care and treatment information in the form of claims and encounter data is comprehensively combined in a patient's claims and billing history."

Adding device identifiers to claims would fill a key gap

CMS' efforts to have patients access their claims data and provide researchers with this information, while laudable, omit one critical element particularly important for the Medicare population. Currently, claims only indicate that a particular procedure was performed—for example, a total knee replacement—but not the brand and model of implant used. Just as with the gap in specificity in the Open Payments program, adding the device identifier to claims can provide the product-level detail to give patients, clinicians, and researchers additional information on the medical technology used to sustain life and support care.[35]

Along with equipping patients with this information, adding device identifiers to claims would help detect problems sooner—averting patient harm associated with faulty implants. Some medical implants, according to analyses of data submitted to FDA, have accounted for tens of thousands of patient injuries—including death.[36]

Incorporating device identifiers in claims can also generate savings. The HHS OIG has found that the failures of just seven types of cardiac implants cost Medicare $1.5 billion to treat affected patients, and an additional $140 million directly to beneficiaries in out-of-pocket costs. OIG recommended the addition of device identifiers to claims to detect these problems sooner, saving lives and money.

This policy also has support from the Medicare Payment Advisory Commission and other groups from across the health care system—including health plans, large hospital systems, clinical societies that represent physicians who implant these products, patient groups, and many other organizations.[37] Adding device identifiers to claims has also generated bipartisan support in Congress. The private committee—called X12—responsible for maintaining the standard claims transaction used by Medicare, Medicaid and other health plans has issued draft recommendations to add device identifiers to claims as part of the next update to the transaction.

For CMS to effectively meet its objectives of ensuring that patients have access to their data—including from claims—and providing researchers with information to evaluate care, the agency should ensure that claims contain critical information on the products used, especially given that Medicare beneficiaries frequently receive implanted devices. Consequently, CMS should further advance this commonsense policy by supporting the addition of device identifiers to claims in the final X12 recommendation and adopting this change through rulemaking.

Patient access to health data, interoperability improves care coordination

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CMS has recently issued regulations to improve patient access to some of their health information, such as records held by insurance companies. To further accelerate that goal, CMS in the PFS issued an RFI seeking comment on steps the agency could take to provide patients with persistent and immediate access to their health data and to address patient matching challenges.

APIs can support persistent and immediate access to information

In recent years, CMS has issued regulations aimed at improving patient access to their health information, including through the launch of MyHealthEData—a cross agency initiative to give individuals control over their data. For example, as part of MIPS, CMS requires that health care providers grant patients access to their medical information through a mobile application of their choice, ensuring that individuals will be able to access their record remotely no matter where they are or when they need the information. In this RFI, CMS seeks comments on how to make it easier and faster for patients to access their information. Specifically, CMS requests information on how to ensure both immediate (e.g. within one business day) and persistent (e.g. that the individual would not have to re-demonstrate their identity) access to data.

Meeting CMS's goal of immediate and persistent patient access to data requires the use of standard application programming interfaces (APIs), which are software tools that allow different technologies to more easily communicate. For providers to use APIs effectively to communicate information, data should be represented in a standardized format—which allows different health systems using a variety of EHR vendors to exchange records more effectively. The Office of the National Coordinator for Health Information Technology (ONC), the agency that regulates EHRs, recently issued proposed regulations that include new proposals for EHRs to have standards-based APIs that can allow for the easy access, exchange, and use of health data. If finalized as written, EHR software developers would have approximately two years from publication of the final rule to implement APIs using the industry agreed-upon Fast Healthcare Interoperability Resources (FHIR) standard in their technology. By using FHIR—as well as associated implementation guides that describe further how data should be represented—developers and providers will be able to exchange information more easily.

CMS should continue to work with ONC to ensure that, where possible, health data are standardized and shareable via APIs. ONC developed the proposed U.S. Core Data for Interoperability (USCDI), a set of data that all EHR vendors must make available via APIs. CMS should work with ONC to expand the USCDI to more data elements, such as radiographic images or other data that are important but difficult to exchange.

In addition, CMS requests comments on whether the agency should grant health care providers a MIPS bonus for adopting standards-based APIs, as called for in ONC's rule, prior to the requirements for the use of these tools taking effect in approximately two years. Pew supports MIPS bonus payments for early implementers of APIs that meet the proposed ONC criteria.

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CMS can take further steps to improve patient matching

CMS also requests information on actions that the agency can take to improve patient matching, which refers to the ability to link records for the same patient across different sites of care. In issuing this RFI, CMS correctly recognizes that to achieve interoperable exchange of medical data, health organizations must also know that they are communicating about the same person. Presently, up to half of the information exchanges made by health care organizations may fail to accurately match records for the same patient.

To accurately match records held at different health care facilities, organizations typically compare patients' names, dates of birth, and other demographic data to determine if records refer to the same individual. Health care facilities use algorithms to conduct these matches, and also employ staff to manually review records. This process often fails to accurately link records because of: typos entered into the system; similarities in names, birth dates or addresses among different patients; changing information, such as when individuals move or get married; among other reasons.

Pew research has shown that the Department of Health and Human Services (HHS) can take two steps to improve patient matching:

- First, HHS should require the use of standards for certain demographic data elements. In Pew-funded research published in the *Journal of the American Medical Informatics Association*, experts at Indiana University studied whether the standardization of different data elements improves patient matching rates.[38] The research revealed that the standardization of address to the standards employed by U.S. Postal Service (USPS)—which details the preferred abbreviations for street suffixes and states, for example—would improve match rates by approximately 3 percent. An organization with a match rate of 85 percent could see its unlinked records reduced by 20 percent with standardization of address alone. One technology developer indicated that this would help their system match an additional tens of thousands of records per day. Separately, standardizing last name to the standard used by the Council for Affordable Quality Healthcare—while showing limited utility on its own—would further improve match rates when coupled with address standardization. The research indicated that standardizing last name in conjunction with address could improve match rates from, for example, approximately 81 to 91 percent, which would reduce the number of unmatched records by half.
- HHS should encourage greater availability of other regularly collected demographic data elements for patient matching. ONC currently requires EHRs to make some demographic data—such as name and birth date—available for matching. However, health records contain other demographic data routinely collected that aren't typically used or made available to match records. For example, research published in 2017 showed that email addresses are already being captured in more than half of patient records.[39] The documentation of email is likely higher today given the adoption of patient-facing tools,

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like portals, that often require emails to register. Greater use of data elements—like email address—could improve patient matching rates.

CMS can take several steps to advance enhanced data standardization and availability of more elements for matching.

- *Use payment policies*: CMS could issue regulations to add patient matching to payment policies. For example, CMS could require demographic data standardization and availability as part of the conditions of participation (CoP) for Medicare. Such an approach would mirror a proposed CoP from CMS to require health care providers to notify primary care physicians when their patients are admitted to, discharged from, or transferred (ADT) from the hospital.[40] Both the ADT notifications and effective patient matching support care coordination, which in turn can improve the safety and quality of care. Similarly, CMS could embed patient matching requirements into the Promoting Interoperability program, through which hospitals and health care providers obtain points toward quality scores that affect reimbursement. CMS could add patient matching requirements as a prerequisite to participation in the Promoting Interoperability program (much like how the agency requires the use of EHRs certified to certain standards), embed patient matching as a stand-alone objective, or include it in objectives related to the sending and receiving of health information. CMS could include patient matching requirements as necessary to obtain some points under the program or as bonus points. However, given that the benefits of address standardization and more data for matching only accrue if implemented widely, a bonus point-based approach would likely not achieve the full potential of this approach.
- *Enter a cross-agency MOU*: CMS could enter into a memorandum of understanding (MOU) with ONC and USPS for the agencies to prioritize patient matching in a synchronous manner. Such an MOU could ensure that—for example—ONC requires EHRs to format address according to the USPS guidelines, and for the Postal Service to allow the health care industry to use its web-based technologies to convert addresses into the correct standard for non-shipping purposes.
- *Coordinate with ONC*: Finally, CMS could coordinate directly with ONC to add patient matching requirements to its regulations. In response to an ONC RFI on patient matching earlier this year, many organizations—from health plans to EHR developers to hospitals—urged the agency to adopt greater standardization of data.[41] CMS should work directly with ONC to encourage EHR developers to advance these patient matching approaches.

By taking these steps—or a combination of them—CMS can accelerate data-driven policy reforms to improve patient matching.

Data outside clinical settings provides necessary context

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CMS also requests comment on ways to capture and use patient generated health data (PGHD)—such as data from personal devices, including wearable fitness trackers. However, PGHD can also include other, critical information, such as advance directives, birth plans, or other documents describing care.

Providers often base their care decisions on information collected in health care settings, such as vital signs, symptoms, and lab results. While this information is essential, data collected outside the clinical visit can provide additional context and reduce critical information gaps, such as recent changes in the patient's condition or messages from the patient about the kind of care they would like to receive. Wearable fitness trackers or sensors can provide an opportunity to monitor and track patients' activity, which could help improve care management. And, birth plans can impact the way patients obtain care during labor.

While many EHRs have the ability for patients to receive information—such as on their smartphones—these systems typically don't support the ability of individuals to contribute information, such as flagging errors or providing data in a standard manner. Allowing this write-access capability would enable patients to update their information, such as address or medications, or directly communicate with their care team.

CMS should work with ONC to ensure that patients have the ability to contribute data on their care. That capability requires data to be captured electronically in a standardized way, so it is more easily interpreted and displayed to clinicians by the receiving EHR. Otherwise, information provided by patients may not be effectively integrated into their medical records. CMS and ONC have already advanced standard APIs to help extract information from EHRs in a uniform way; the agencies should take a similar approach to support the input of data back into EHRs.

To best support this capability, the data provided by patients should also have provenance information, which indicates its origin. By including provenance, future providers would know whether the data originated from the patient, another clinician, or from a device.

CMS should embed EHR safety into its policies

In the PFS proposed rule, CMS also seeks information on how the agency can encourage the safe use of EHRs, as the layout, design and implantation of systems can contribute to medical errors. Specifically, CMS seeks information on how the agency can encourage adoption of the Safety Assurance Factors for EHR Resilience (SAFER) Guides—which document a series of best practices for health care organizations to self-assess their medical record systems—or alternatives by providers, including by awarding bonus points to Promoting Interoperability score.

EHR safety challenges can arise due to—in part—system usability, which refers to whether clinicians can efficiently and effectively interact with the technology. Usability challenges can

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result from the initial design of systems, how they are customized by facilities, unique workflows, user training, and other factors.[42] Usability-related safety problems can emerge due to confusing interfaces to complete tasks, the need to develop workarounds, an overabundance of unnecessary alerts, and many other issues given the central role that EHRs increasingly have in helping clinicians order procedures, review health information, and obtain decision support.[43] For example, research published last year in *Health Affairs* showed that EHR usability contributed to approximately a third of 9000 medication errors examined across just three health care organizations that care for children; 609 of these usability related events reached the patients.[44] In one case involving the birth of newborn twins, clinicians could not create a record for one of the infants, which delayed a necessary blood transfusion that was ultimately ordered for the sibling as a workaround. [45] In another case, a clinician entered a child's weight in pounds when the EHR was configured in kilograms, doubling the child's weight and resulting in the patient receiving twice the appropriate medication dose. [46]

Opportunities for CMS to improve EHR safety
Pew supports CMS' approach to use the Promoting Interoperability program—either through attestation or reporting requirements—to encourage health care provider adoption of strategies to improve the safety of EHRs. CMS could consider the following options:

SAFER Guides
ONC publishes nine SAFER Guides on a range of EHR-related safety topics. Despite their ability to assist with implementation of EHRs in all types of health care facilities, their uptake has been low; out of eight organizations surveyed, only 25 of 140—or 18 percent—of the recommendations were fully implemented, according to a study published in April 2018.[47] In the RFI, CMS requests input on how to advance the use of two of these SAFER Guides: High Priority Practices and Organizational Responsibilities.

The High Priority Practices guide focuses on factors that represent the greatest risk and suggests broadly applicable actions that health systems can take to address challenges, such as creating processes for EHR downtime. For some of the aspects of this guide, CMS could obtain attestation—such as whether downtime plans exist. For other aspects of the guide, CMS could require numeric reporting. For example, one practice in the guide encourages hospitals to measure the number of orders submitted on paper as opposed to through the EHR. CMS could request the percent of orders submitted electronically (with the numerator being electronic orders and the denominator being all orders).

The second guide, Organizational Responsibilities, focuses on the steps that each individual—from leaders to everyone involved in direct patient care—can take to improve safety. For example, the guide calls for the creation of a safety committee that includes doctors, nurses, and others involved in the care process. Any major decisions regarding the EHR should involve this committee. CMS could provide a MIPS bonus for the facilities that electronically attest to adherence with these practices.

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CMS could increase use of the SAFER Guides by providing Promoting Interoperability points to hospitals and health care providers that practice in a facility that used the guides within a given fiscal year.

Use of usability testing tools

Health care organizations could also use testing tools to assess the usability and safety of their systems. For example, the Leapfrog Group—a non-profit organization founded by large employers to improve safety, quality and affordability in health care—developed a computerized physician order entry (CPOE) tool to assess EHRs' ability to alert clinicians to common, serious, and sometimes fatal medication ordering errors. The tool examines the implemented EHR within hospitals to provide both an overall score and for ten subcategories that represent areas where serious adverse events can occur.

The Leapfrog CPOE Tool—which has been endorsed by the National Quality Forum (NQF) and has been part of Leapfrog's annual, voluntary hospital survey since 2008—is already widely used and therefore would not introduce a significant new burden on many health care providers. Nearly 2000 inpatient facilities in both 2017 and 2018 completed the test.[48] An ambulatory module is in development and expected to be publicly released in 2021.

The use of the Leapfrog tool has been associated with increased ability to detect medication errors. In research published in July 2019, new data shows that EHRs that engaged in annual testing throughout an eight-year term saw their EHRs' ability to detect medication problems rise to 70.3 percent in 2016. In contrast, those who tested at least once but not every year over that same term only had a score of 61.6 percent. This difference shows that a dedicated focus on quality and safety—including through the use of the Leapfrog test—can help avert harm.

Given the correlation of frequent testing with better error detection, CMS can encourage use of the Leapfrog tool—or something similar—so that providers are aware of the gaps in their system. With the release of the ambulatory module in 2021, CMS could accelerate adoption among physician offices and outpatient clinics. CMS could both offer bonus points in the Promoting Interoperability program for health care providers that use a test in a given year, and—in the future—offer additional points for improving the score over time, which would promote the implementation of similar steps that can enhance quality and safety.

Adoption of best practices

Many organizations have also developed best practices for health care providers to implement that can improve the safe use of EHRs. For example, last year, the American Medical Association, MedStar's National Center for Human Factors in Health Care, and Pew released a report that provides health care providers and EHR developers with best practices to improve the usability and safety of their EHRs.[49] Examples of best practices include establishing codes of conduct, creating safety teams, implementing training programs, and using rigorous use-case test scenarios to identify EHR challenges that could introduce harm.

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CMS could encourage adoption of the best practices by offering Promoting Interoperability bonus points for health care providers that attest to implementing the best practices.

In addition, organizations that accredit EHRs may soon develop safety-specific programs to certify that these technologies were developed in a manner to detect hazards prior to implementation. Under such a system, these organizations may offer voluntary accreditation for EHRs that meet certain safety-specific requirements. CMS could consider providing health care providers with Promoting Interoperability bonus points if using EHRs that obtain a safety-specific accreditation.

Finally, MedStar and Pew continue to collaborate on identifying opportunities to improve the safety and usability of EHRs, including through the identification of steps that hospital accreditation organizations—such as the Joint Commission—can take. CMS, in working with these accreditation organizations, could also advance many of these best practices.

EHR safety measures

CMS could also adopt existing EHR safety measures. In February 2016, NQF published a report that identified nine key health information technology-related safety areas with concepts that could be adapted into CMS measures. For example, the report provides concept ideas on clinical decision support; user-centered design; system downtime; and other areas. CMS could provide a Promoting Interoperability bonus points for attesting that the facility has established an EHR testing program and that a percentage of the EHR users undergo that test. CMS can provide an additional bonus the following year if the test scores improve.

NQF has also endorsed an additional measure that uses audit or log file data—the digital record of what happens within an EHR, such as the ordering of a medication and the retracting of that order—related to when clinicians order medications on the improper patient.[50] Implementation of this measure provides another means to improve safety within an EHR. CMS could provide Promoting Interoperability bonus points for facilities that implement the retract and reorder measure.

As CMS examines how to incorporate EHR safety into the Promoting Interoperability program, these ideas offer steps that health care providers can take to reduce harm associated with the use of technology.

Conclusion

In these proposed regulations, CMS makes strides to improve treatment for patients with OUD and advance greater transparency in the financial relationships between medical device manufacturers and clinicians, and also seeks comment on opportunities to enhance the safety and coordination of care.

In finalizing the regulations and reviewing comments to the RFIs, CMS should:

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- Review existing evaluation and management codes to ensure they adequately capture all the activities necessary to support prescribing OUD medications and coordinate care in office-based settings;
- Cover OTP intake activities, such as initial physical examination, initial assessments, preparation of a treatment plan, and periodic assessments;
- Review existing evaluation and management codes and consider paying for care coordination within OTPs;
- Propose payments for OUD treatment initiation in emergency departments in future rulemakings;
- Consider payments for emergency department-specific activities to ensure referrals to long-term treatment and follow-up care after care begins;
- Require medical device manufacturers to submit product-specific information to the Open Payments database;
- Incorporate medical device identifiers to health insurance claims;
- Grant patients persistent and immediate access to their health data;
- Provide a payment bonus for health care providers that accelerate adoption of standards-based APIs;
- Support greater standardization of demographic data used to match records located in different facilities;
- Coordinate with ONC to enable patients to input data into their health records; and
- Offer payment bonus points to health care providers that prioritize the safety of EHR systems.

Thank you for the opportunity to comment on these proposed regulations. Should you have any questions or if Pew can be of assistance, please contact me at (202)-540-6392 or acoukell@pewtrusts.org.

Allan Coukell
Senior Director, Health Programs
The Pew Charitable Trusts

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