May 31, 2019

The Honorable Seema Verma
Administrator
Centers for Medicare and Medicaid Services
US Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Submitted electronically via: http://www.regulations.gov

RE: 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,

    OCHIN applauds the Center for Medicare and Medicaid Services’ (CMS’s) extensive work to advance interoperability and reduce information blocking. We recognize CMS’s efforts to drive stakeholder conversations, improve health IT adoption in post-acute care settings, and improve patient matching algorithms. OCHIN appreciates the opportunity to submit our previous comments, and the recognition for our recommendations in the past. We are further grateful for the opportunity to supply CMS with a response to this proposed Rule.

    OCHIN is a 501(c)(3) not-for-profit community-based health information technology (HIT) collaborative based in Portland, Oregon, that supports health care providers who treat the nation’s most vulnerable patients. OCHIN helps elevate health information exchange and health IT for a large percentage of patients who are being treated by safety net providers across the nation. Our goal is to provide a national voice for safety net providers within health care technology and information exchange. These providers, and the population they serve, are underrepresented in the data sharing and data blocking conversation.

    As a national network that supports over 500 health centers across the country, OCHIN scales health IT services through hosted electronic health records (EHRs), telehealth services, and other professional services to our members. To provide the highest level of care to our unique patient population, OCHIN has grown to be one of the largest movers of health data in the nation. Since 2010 we have moved over 100 million clinical summaries, and we continue to innovate within health information exchange and expand our partnerships to improve care coordination for especially complex and vulnerable patients. CMS directly pays for 53% of OCHIN’s claims; 46% by Medicaid and 7% by Medicare, while 26% of our members’ patients are uninsured.
OCHIN’s comments reflect our strong understanding of, as well as success in, data privacy and security, and their pivotal role in interoperability. With a continuously evolving system of patient data and treatment needs, regulations must also advance to enhance patient care and safety.

**OCHIN Overall Comments on the CMS Interoperability and Patient Access Proposed Rule:**

OCHIN strongly agrees with the goal of interoperability for treatment purposes and improved care coordination. We applaud the extensive progress made onboarding providers to certified EHRs through the EHR adoption programs and urge CMS to continue to supply this funding to ensure those left behind or on poor EHR systems become fully interoperable. These efforts have been pivotal in getting interoperability to its current state, and therefore must continue with the inclusion of those left out of Meaningful Use. OCHIN urges CMS to expand their efforts to include all other providers left out of the interoperability efforts in the past, such as behavioral health providers, long term care providers, nursing homes, and dental providers. This would allow for providers to access truly complete medical records to better coordinate and deliver successful care. We urge CMS to increase funding and incentive programs to bring all providers to the interoperability table.

To support greater interoperability, OCHIN continues to work with our members and partners to expand reliable broadband infrastructure for optimal delivery of care. Many health care providers are left out of the interoperability conversation due to lack of sustainable, consistent broadband connectivity, and lack of interoperable EHRs. Many safety net providers operate older and outdated EHRs, making them less interoperable overall. The movement towards a value-based care system and evolution of virtual care has incredible potential to improve treatment and outcomes in areas that remain essentially disconnected – rural and underserved areas – with the least access to broadband services. OCHIN encourages CMS to provide funding to innovate the systems of small providers and health centers, supporting better EHRs and virtual care integration overall.

The far reaches of CMS provoke OCHIN to echo the protections suggested in our ONC comments. Efforts to empower patients with their data has exposed elements of concern which could be softened with additional protections for patients and providers. We urge educational programs for patient consent and understanding, and additional safeguards to providers as they transfer data from a regulated to an unregulated environment.

Finally, OCHIN suggests innovative models per CMS’s RFI, to improve public health and expand virtual care as well as recommendations regarding the oversight authority and regulation of non-HIPAA related entities. We look forward to working with CMS on these issues in the future to improve patient care and delivery to vulnerable populations.

**No Provider Left Behind/ Interoperability**

While interoperability has been advancing, not all providers have been included in this transition to electronic health data exchange. Due to dental providers, acute care hospitals, critical access hospitals, behavioral health providers, and others being carved out of the EHR Incentive Program, there are still providers incapable of participating in advances in interoperability due to their current poor EHR services or their insufficient broadband access, and the lack of funding to improve either. These costs to modernize
or upgrade the health center EHRs are directly borne by safety net providers that can least afford these costs or bear the disruption to practices.

OCHIN strongly suggests these providers remain a focus throughout the interoperability efforts, and that funding or incentive programs be created to get all providers onto a level playing field. This achievement is critical for successful patient care, and to prevent rural and underserved communities from being excluded from interoperability advancements. Support would be best provided in funding for technological assistance to help providers upgrade to more reliable and interoperable systems. Higher quality systems are expensive to implement and maintain but are critical to achieving CMS’s goals of interoperability and reporting requirements.

OCHIN is further concerned that continuous upgrades to these systems unnecessarily increase costs, widening the gap between safety net and small providers and those already onboarded to certified interoperable EHR systems. The EHR technology evolution is creating a consolidation within the EHR marketplace, which places additional pressure on safety net and small providers to upgrade their EHR systems, with no financial support. OCHIN encourages CMS to fund and support safety net and other primary care providers to adopt upgraded platforms that drive better interoperability.

Innovation Models (Focus on Funding)

As a health learning collaborative, OCHIN implements innovative technology and then studies what works and what does not, based upon the impact to our population such as immunization issues, behavioral health, substance use disorder, and access to virtual care. OCHIN currently supports over 25 public health departments across the country, meeting their unique needs and delivering health care to their communities. We are always seeking better methods to ensure patients do not have to commit to additional steps and unnecessary visits to get the care that they need, while keeping costs affordable. OCHIN recommends focusing public health innovation through EHR integration for complete and interoperable patient records to improve patient outcomes, public health reporting, and reduction of provider burden.

Bidirectional Immunization

OCHIN is a national leader in public health reporting and immunization registries, working extensively across the nation piloting bidirectional immunization exchange directly within the EHR for safety net providers. Our members can speak to the importance of having this capability directly available and unencumbered by additional health information exchanges that increase cost and burden. Integrating these capabilities directly into the EHR reduces provider burden and improves reporting rates. We encourage CMS to focus efforts as charged under Section 4005 (a) and (b) of the Cures Act, specifically on interoperability as it pertains to the “bidirectional exchange” between EHRs and registries, including clinician-led clinical data registries.

OCHIN strongly supports state use of direct and free bidirectional exchange with immunization registries. We believe with the recent outbreak of measles and the lack of immunization records to determine the true state of this emergency, a bidirectional immunization program has proved to be a vital component missing from a clear path forward. Bidirectional immunization paired with an increase in the number of clinics in underserved areas to administer safety net vaccinations could greatly curb this and
other future outbreaks. In partnership with the CDC, OCHIN could help CMS move the needle on this outbreak.

Currently, there are many rural and safety net providers who can only participate in the immunization program via paper and fax, increasing provider burden in recording, storage, and transfer. Until there is a national electronic system for this data, bidirectional immunization programs must be funded and successfully implemented directly by every state. Additionally, requiring these systems to run through an HIE will only add additional burden to providers. These programs should be national or state-run, cost neutral, and bidirectional for successful outcomes. To achieve this, states should be provided additional funding to support the build-out of bidirectional exchanges at the state level, and safety net providers should be financially supported to connect directly to them and provided with technical assistance to integrate data exchange within their EHRs.

- **Virtual Care**

  As an entity that supports providers in rural and underserved areas, the benefits of virtual care to improve patient outcomes has become clear and undeniable. Although there are many efforts pushing virtual care forward, there are still a number of hurdles to overcome. These include insufficient and unsteady reimbursement, provider and specialist shortages (licensure), insufficient broadband infrastructure, and a need for extension into patient homes.

  Medicare is working quickly to properly reimburse patients for their virtual care, mostly in rural areas through primary care providers. However, state Medicaid policies have been slower to change and vary dramatically. OCHIN strongly encourages CMS to ensure state Medicaid regulators update policies for payment parity. OCHIN and our members have piloted innovative virtual care programs, such as eConsult services, with managed care partners. The result was the ability to improve both patient and provider experience through these innovative virtual care platforms, reducing the economic impact by saving time and mileage. Without reliable rates of reimbursement, patients are less inclined to take advantage of this opportunity, inevitably increasing burden and cost.

  Although provider shortages are more common in rural and remote areas, it is also an issue in cities across the country, especially in the Medicaid community. Virtual care allows patients anywhere across the nation to connect to a specialist as needed, permitting the specialists to screen patients, and to consult prior to their appointment to determine if the specialist’s care is necessary. A study done in 2015 in the *British Journal of Ophthalmology* showed that telemedicine reduced wait times for patients by almost 90%.¹ OCHIN encourages CMS to support innovation within virtual care platforms, such as eConsults, to bridge these shortage gaps.

  Capturing patient visits and consultations within the electronic health record via the virtual care platforms is vital to full care coordination and CMS’s interoperability objectives. Therefore, we also encourage CMS to fund technical assistance to small practices and community health centers that treat Medicaid patients for integration of virtual care platforms within a fully interoperable EHR. Health centers need assistance to ensure the platform is supported and connects successfully to the patient record.

A final innovation suggestion for CMS would be to assist in the process by which specialists are permitted to treat patients across state lines. Each state has its own licensure and credentialing programs that permit visiting specialists from other states to care for patients. These programs are challenged with delays and bureaucratic red tape which result in provider shortages. Streamlining this process and requiring admission with certain terms would benefit patients in areas suffering from shortages by allowing clinicians to provide virtual care regardless of location. OCHIN encourages CMS to support evolution in this space, both at the state regulatory level and with vendors delivering virtual care platforms, to speed up credentialing and licensing of providers.

- **Social Service Resource Locators**

An important and burgeoning aspect of integrated care relates to capture and support of social determinants of health (SDH), or social risk factors, as part of a patient’s medical history. Integrating care and supplying each provider with a complete medical record is critical to provide patients with coordinated care. OCHIN encourages CMS to support the integration of social services resource locators (SSRLs) within an interoperable EHR platform. Providers are increasingly asked to screen patients for SDH, recognizing that their incorporation can lead to more efficient and informed care. Direct integration to supply assistance via SSRLs also can help to reduce provider burnout. OCHIN further encourages CMS to adopt national standards for SSRLs. Allowing providers to connect patients to social services without leaving their EHR workflow will create a win-win for both patient and provider.

Having complete medical records that include social service referral and utilization would be an enormously valuable element to public health studies and efforts, allowing researchers and agencies to better understand complex patients and the value of care. OCHIN suggests incentivizing this collaboration. Pairing this system with improved reimbursement models, virtual care delivery, and increasing the size of community-based networks for support interventions will ease the patient and provider burden and improve patient outcomes.

**Attestation Statements**

We have research that shows quality of care is mischaracterized in safety net clinics based on standard assessments. Currently, the quality of care assessment often does not adjust for SDH. Our findings suggest that providers in safety net clinics, who treat patients with high levels of social complexity relative to the general U.S. population, may benefit from having their performance metrics adjusted using SDH measures. The use of quality metrics unadjusted for SDH may penalize providers who serve vulnerable populations, ultimately resulting in fewer options for care among those individuals who need it most, increasing existing health disparities. Finally, a review period for MIPS reporters before data is publicly posted as part of the annual process would be beneficial.

**Provider Protections**

Interoperability is critical for treatment. The premise of the CMS Rule is that patients can own and direct their data. However, there must be provider safeguards and safe harbors in place to protect the transfer of data from a HIPAA-regulated provider environment to a non-HIPAA-regulated environment. Safeguards must be codified in statute to ensure liability is attached to the entity that misuses or sells patient data, as opposed to the provider. We strongly believe recent rules by ONC and CMS are the
makings of a two-tiered system that will render HIPAA and its protections moot. OCHIN ultimately suggests HIPAA be applied similarly to those currently handling personal health information (PHI) to those proposed to push PHI down to patients.

OCHIN suggests CMS financially support small providers and health centers treating vulnerable patients for navigating the liability issues that arise from this transfer of data, the application of which could be based on the staffing level, rural classification, or number of patients within the safety net. Without this additional support, small and safety net providers who are vital to the nation’s overall public health are being placed in a precarious position, at risk of being the target of blame from patients as they are the point of data collection. With such tight resources, these providers may be forced to choose between providing care or investing in legal assistance.

Patient Protections

The implications of the health data sharing outlined in the ONC and CMS rules are of great concern to OCHIN. Even HHS has acknowledged that “individuals who share their health information with NCEs [non-covered entities] might not fully understand where the protections afforded by HIPAA begin and end… [and] may inadvertently consent to unanticipated types of information sharing and use by NCEs collecting their health information.”2 We are concerned CMS and ONC have not sufficiently addressed the data and privacy concerns that accompany permission for NCEs to gain access to patients’ health data.

Patients require and deserve protection against those phishing for valuable medical information for non-medical purposes, especially vulnerable patients such as seniors and those within the safety net. In the case that HIPAA is not extended to include NCEs, protections must include strict rules including a prevention on the sale of patient data, and strong transparency laws that require an app developer or other NCE requesting health data to disclose their intended use of the data prior to the patient consenting to its transfer.

Furthermore, although the Office of Civil Rights (OCR) issued a request for information on HIPAA, which included questions about what changes to make to support interoperability, this was prior to the proposed CMS and ONC rules and was not echoed in either of the subsequent proposals. We eagerly await interim rules that outline how HHS will regulate NCEs and establish necessary patient and provider protections.

As the health IT app ecosystem continues to evolve, patients need to be provided clear guidance and understanding of the extent of their consent when transferring their PHI to an NCE. Patient consent agreements must be easy to understand. Agreements for use of these apps are often in complex legalese, small text, and not available in all languages. As OCHIN supports a population that speaks 132 languages, this is of great concern to our members and their patient population.

Another obstacle within the safety net community is the broad spectrum of medical literacy and level of reading comprehension. Although EHRs are quickly expanding the languages in which they serve patients, 24 U.S. Department of Health and Human Services. (2016, June 17). Examining oversight of the privacy & security of health data collected by entities not regulated by HIPAA. Retrieved from https://www.healthit.gov/sites/default/files/non-covered_entities_report_june_17_2016.pdf.
patients, it is simply not reasonable to ask vendors to comply with all language needs in 24 months. It is even less likely NCEs will support patients’ language needs.

Education on patient consent is critical to ensure patients can protect themselves and advocate for their own interests. A 2018 Deloitte study showed that 91% of the population does not take the time to read terms of service, with a rate of 97% among those age 18-24.\(^3\) Where an incentive, financial or otherwise is presented to patients, this rate will surely be even higher. For the vulnerable population, this incentive would draw swaths of health data, which is more likely to be used against the patient, whether it results in higher insurance premiums, denial of public services, etc. OCHIN believes without limits on NCE PHI use, this may lead to further bias and disparities in the health care system against the nation’s most vulnerable.

In addition to strict rules on NCE’s uses of data, OCHIN urges CMS to appropriate additional funding for educating patients on the responsibilities and risks associated with providing NCEs with permission to their health data. These should come in the form of both public service announcements prior to the enactment of this rule and funds appropriated directly to health centers to educate their patients on app consent. These additional efforts could help alleviate negative impacts on patients and providers.

**FTC as Regulating Entity**

Section 5 of the Federal Trade Commission Act\(^4\) codifies the FTC’s authority to serve as the regulatory oversight body when NCEs disclose an individual’s health data in a manner inconsistent with the privacy notice and terms of use or are engaged in discriminatory or predatory activities that harm consumers.

With this extreme influx of health data transferring to NCEs with the finalization of the ONC and CMS rules, it is critical that more well-funded and patient-focused oversight be established. The above-referenced HHS report states that current oversight mechanisms do not provide the same type or level of protection as HIPAA. When both covered entities and NCEs are handling the same information, further protections must be created, or HIPAA expanded lest it becomes obsolete.

The proposed enforcement by the FTC to simply ensure these entities do not violate their own terms and conditions without further restrictions does not increase transparency, protect PHI, or prevent deceptive practices the patient may have unknowingly agreed to. It is imperative that CMS work with a more investigatory body to create and enforce more strict guidelines and standards for privacy with strong legal ramifications for violations. OCHIN suggests appointing the OCR under HHS, or the HHS Office of the Inspector General as an alternative body or to supplement the FTC’s oversight. These entities have experience with HIPAA or identification of systemic weaknesses giving rise to nefarious abuse of consumers.

---


\(^4\) 15 U.S.C. § 45(a) (Section 5 of the FTC Act).
Further, it is OCHIN’s recommendation that injunctions and expulsions are the consequence of serious violations as opposed to fines. With the financial incentive to selling patient data, fines may be viewed as the price of doing business as opposed to operating as a disincentive.

Finally, OCHIN is concerned that there are entities that may come into contact with once-HIPAA regulated health data and not fall under the purview of HIPAA, the NCE oversight body, or state law. These entities would be free to collect, share, or use health information which could put patients at risk. Safeguards must be put into place to prevent data from reaching these entities outside of regulatory oversight.

**Patient Matching**

Although CMS is prohibited from adopting a unique patient identifier (UPI), there is a clear need to enhance patient identification efforts to improve patient safety, coordinate care, and advance interoperability. To underscore the problem, in 2016, Harris Health System in Houston, Texas reported it had 2,488 records with the name “Maria Garcia;” of those, 231 shared the same birthdate, suggesting some of them refer to the same individual.\(^5\) Notably, if all health care organizations collected certain pieces of demographic data uniformly, patient-match rates would increase significantly. OCHIN strongly recommends that providers should have access to CMS claims data, as this could dramatically improve patient matching.

**CMS and ONC Timelines**

To strengthen CMS’s and ONC’s proposed rules and better support the interoperability intent underlying these rules, stakeholders and affected entities require ample time to comply with reasonable deadlines paired with adequate outreach and education initiatives for patients. Additionally, these rules have overlapping timelines which are not yet fully aligned. Given the magnitude of these proposed changes, we encourage CMS and ONC to publish interim final rules rather than final rules to include stakeholder recommendations and supply a secondary opportunity for additional stakeholder comment prior to the final rulemaking.

OCHIN appreciates CMS’s efforts to modernize and support interoperability. We appreciate your consideration of our comments. Please contact Jennifer Stoll at stollj@ochin.org should you have any questions.

Sincerely,

Jennifer Stoll  
EVP, Government Relations and Public Affairs