



**STATE OF WASHINGTON
HEALTH CARE AUTHORITY**

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June 3, 2019

Seema Verma
Administrator
Center for Medicare and Medicaid Services (CMS)
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, D.C. 20201

Re: Request for comments, CMS notice of proposed Rulemaking

Dear Administrator Verma,

On March 4th CMS published a notice of proposed rulemaking (NPRM) entitled, “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 Advancing Interoperability in Innovative Models.” On the same date, the Office of the National Coordinator for Health IT (ONC) published a companion NPRM entitled, “21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program.”

Washington State Health Care Authority (HCA) reviewed the CMS notice of proposed rulemaking and its potential impacts to the Medicaid program. Washington is very interested in supporting CMS and our community partners with creating, implementing, and sustaining innovative ways to securely share health information. Overall, HCA is pleased to see CMS approach this rulemaking activity through the lens of providing patient access and control to their health information. However, we are concerned that there is a layer of support infrastructure that needs to be in place to accurately, securely, and effectively transfer information at the scale and velocity that is contemplated in this rule proposal. Some of this additional infrastructure is in the form of guidance and clarification from CMS on the proposals which makes the implementation timeframes of January and July 2020 infeasible. We welcome the opportunity to improve data sharing and availability on behalf of our clients, and would be pleased to partner with CMS on how to design thoughtful upgrades to the system that accomplishes federal goals while maintaining the privacy, security, and integrity of our citizen’s data.

Comments from HCA, the Washington State Medicaid Agency

Section I. Background and Summary of Provisions

Section II. Technical Standards Related to Interoperability

CMS indicates that this NPRM is the “first phase of proposed policies centrally focused on advancing interoperability and patient access to health information... this is an important step in advancing interoperability, putting patients at the center of their health care and ensuring they have access to their

health information. We are committed to solving the issue of interoperability and achieving complete access to health information for patients in the United States (U.S.) health care system, and are taking an active approach to move participants in the health care market toward interoperability and the secure and timely exchange of health information by proposing and adopting policies for the Medicare and Medicaid programs ...”.

The NPRM proposes to define “interoperability” with respect to health IT as technology that “enables the secure exchange of electronic health information with, and use of electronic health information from, other health IT without special effort on the part of the user. It also allows for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable state or federal law and does not constitute information blocking as defined in section 3022(a) of the PHSA.” CMS believes this definition of interoperability is useful as a “foundational reference for our approach to advancing interoperability and exchange of electronic health information for individuals throughout the United States, and across the entire spectrum of provider types and care settings with which health plan issuers and administrators need to efficiently exchange multiple types of relevant data.”

CMS describes several challenges toward achieving interoperability identified through stakeholder feedback, including: lack of standardization (including the lack of needed interface and content standards), lack of adoption/use of certified health IT “among post-acute care providers”, and lack of harmonization between federal and state privacy and security standards.

HCA Comments on Sections I and II:

- A.** HCA agrees with criticality of putting patients at the center of their health care and ensuring they have access to their health information. HCA supports the proposed definition of interoperability that allows secure exchange, access, and use of electronic health information without special effort on the part of the user under applicable state or federal law.

- B.** HCA shares the belief that the proposed definition of interoperability is a critical reference to advancing health information exchange “across the entire spectrum of provider types and care settings.” HCA believes that advancing the interoperable exchange of information with and by behavioral health providers is essential. In addition, while we agree that limited adoption and use of Certified Electronic Health Record Technology (CEHRT) is a concern by post-acute care (PAC) providers, we also believe that limited adoption and use of CEHRT by behavioral health providers is also a challenge.

Preliminary findings from a recent survey conducted by HCA’s Division of Behavioral Health and Recovery (DBHR) of behavioral health (BH) providers (i.e., those that provide substance use disorder (SUD) and/or mental health (MH) services) indicates that:

- 16 percent of these providers report using paper records;
- less than 50 percent of these providers report using electronic health records (EHRs); and
- approximately 35 percent of these providers report using certified EHR technology.

These findings indicate that BH provider adoption and use of health information technology and CEHRT lags behind adoption and use rates for entities that were eligible for EHR incentive payments under HITECH.

To realize the CMS goal of “advancing interoperability and exchange of electronic health information for individuals across the entire spectrum of provider types and care settings” providers “across the entire spectrum of provider types and care settings” need to have and use technology that enables interoperability and exchange.

CMS describes the need for information exchange on behalf of persons who receive post-acute and long-term care services. HCA agrees with this identified need.

HCA believes that access to BH information is essential for providing needed treatment and population health management:

- Opioid misuse (including prescription opioid misuse) and addiction is a public health crisis across the country, including in Washington State.
- Washington State has the second-highest rate in the nation of adults with serious mental illness (SMI).
- Co-occurring MH conditions and SUD are common. In 2014, almost 40% of adults in the U.S. with a SUD (20 million) also had another mental illness.
- Individuals with BH needs experience frequent transition in care and also have service delivered by multiple care team members who may not be co-located. For example, individuals with BH needs are diverted from incarceration, and frequently admitted to or discharged from emergency departments, acute care hospitals, and/or psychiatric hospitals.

HCA agrees with the following statements in the CMS NPRM:

- “Transitions across care settings have been characterized as common, complicated, costly, and potentially hazardous for individuals with complex health needs” and
- “While interoperable, bidirectional exchange of essential health information can improve these transitions, many long- term and PAC, behavioral health, and home and community-based service providers have not adopted health IT at the same rate as acute care hospitals.”

- C. We agree with CMS that Application Programming Interfaces (APIs), Fast Healthcare Interoperability Resources (FHIR), and the United States Core Data for Interoperability (USCDI) have the potential to solve key problems with interoperability. However, they may prove logistically complex to administer as they become more widespread. In addition, APIs and the USCDI are not consensus-driven standards, and we do not agree with the requested exemption to the National Technology Transfer and Advancement Act.
- D. The instructions for how entities must map USCDI and HIPAA Administrative Simplification transactions to APIs is likely to create an untenable, administratively burdensome system with a significant amount of duplicate work. We request that CMS take an overarching look at how this proposed expansion of APIs interact with existing laws prior to applying these rules to providers and other entities who are already required to trade data in HIPAA-compliant formats. We support

reducing the administrative burden through APIs, but do not believe that this section of the rule, as written, will accomplish those goals.

- E. FHIR is extremely promising, but is a relatively new transaction format. The accelerated timeframe creates a concern that there will not be enough FHIR experts available to meet requirements, and not enough time or funding to effectively train state staff to gain the technical understanding of these new formats.
- F. FHIR also has not previously been a requirement as part of the Promoting Interoperability, formerly Meaningful Use, Program, and a significant amount of infrastructure has been developed by state government entities to leverage the systems that providers and vendors created under those rules. Provider resources will be strained in developing, implementing, and maintaining interfaces to meet the rules outlined in the CMS and ONC NPRM, and many previously developed systems will be neglected, if not abandoned entirely. HCA and other agencies would like guidance as to how funding can be leveraged to enhance these systems to ensure data flows appropriately to support our citizens.

Section III: Patient Access through APIs

- A. The role of state Medicaid Management Information Systems (MMIS) is unclear. Does the rule require all state's MMIS to develop open APIs and make information available to clients within 24 hours of receipt or adjudication of administrative data (adjudicated claims, encounters, provider remittance, etc)? It seems clear that the rule does not require health plan insurers to use Health IT modules to make administrative data available, but the role of a payer's claims adjudication system (including MMIS) is unclear.
- B. Washington State has a large percentage of clients who receive services through a Managed Care service delivery model. HCA receives encounter data from Managed Care Organizations (MCOs) when services have been provided to our clients. Will a state's MMIS be required to make "encounter data" from MCOs available within 24 hours of receipt? There are concerns that these data could appear to conflict with data obtained by a client directly from an MCO, causing client confusion and increasing administrative overhead.
- C. MCOs would have until January 2020, and state Medicaid agencies would have until July 2020, to comply with sections of the proposed rule. This timeframe seems unreasonable, particularly given the need for additional guidance and clarification to be issued by CMS. We urge CMS to address the foundational strategies needed to support this rule and work with States and other entities targeted by this rule to develop appropriate, supportable timeframes.
- D. We applaud the ability to support clients in utilizing applications of their choice to manage their healthcare information. However, there is a significant concern that the API-driven process outlined in the rule will result in data acquired by a third party application without the consent of the client. As stewards of Medicaid data, this brings up significant concerns over our responsibility for and our ability to protect these data. The rule includes language that a covered entity implementing an API must take "reasonable" steps to ensure that an individual's information is only disclosed as permitted – what are "reasonable" steps once an open API is established?

- E. Like CMS, HCA values patient privacy and autonomy over their data. We applaud the goal of this rule in ensuring clients, patients, and citizens have better access to resources which help them understand privacy decisions related to their health data. The approach described in the proposed rule creates a complicated network of patient privacy guidance from federal, state, and private entities. Instead of multiple, potentially conflicting guidelines from separate sources, HCA believes it would be much more appropriate for the Federal Government to develop guidance that entities subject to this rule are required to distribute, supplemented as necessary with state guidance specific to state law. Differentiation in guidance will create more confusion in a complex system that is already difficult for patients to navigate.
- F. HCA's believes that the rule also provides a complex and sometimes contradictory approach to allowing access to patient data resources. The rule does not allow for certification or verification of specific vendors for privacy practices, but entities must prohibit vendors who perform poorly. Agencies must develop guidelines for how a client should choose an application vendor, but cannot verify vendor capabilities. This creates significant legal risk, having to navigate between endorsing or discriminating against products create by private entities while providing enough information for patients to make informed decisions. HCA urges CMS to allow for or create a certification process for vendors that will access patient data resources, or allow for entities covered by this rule to fund independent verification of applications prior to exposing patient information to these platforms.

Section XI: Advancing Interoperability Across the Care Continuum.

Section XII: Advancing Interoperability in Innovative Models.

CMS indicates that it plans to use CMMI authority under section 1115A of the Act to test ways to promote and advance interoperability across the care continuum and in innovative payment and service delivery models to reduce program expenditures, while preserving or enhancing quality of care. CMS indicates that:

- interoperability and health data sharing are critical to the success of new payment and service delivery models that incentivize high quality, efficient care for Medicare and Medicaid and CHIP enrollees; and
- future model development may include: models that incorporate piloting emerging standards; models leveraging non-traditional data in model design (for example, data from schools, data regarding housing and data on food insecurity); and models leveraging technology-enabled patient engagement platforms.

CMS requests comments on:

- A. potential strategies for advancing interoperability across care settings to inform future rulemaking activity (including comments on incorporating certain post-acute care (PAC) standardized and interoperable patient assessment data in the USCDI (U.S. Core Data for Interoperability) and requiring physicians and hospitals to collect and electronically exchange a subset of these PAC standardized patient assessment data;
- B. how HHS can more broadly incentivize the adoption of interoperable health IT systems and use of interoperable data across settings such as long-term and post-acute care, behavioral

health, and those settings serving individuals who are dually-eligible for Medicare and Medicaid and/or receiving home and community-based services;

- C. ways:
 - to test promoting interoperability across the health care spectrum through CMMI models to engage with health care providers and other entities in innovative ways and test concepts that have the ability to accelerate change in the U.S. health care system; and
 - in which CMMI may further promote interoperability among model participants and other health care providers as part of the design and testing of innovative payment and service delivery models;
- D. specific policy strategies HHS could adopt to deliver financial support for technology adoption and use in these settings;
- E. measure concepts that assess interoperability, including measure concepts that address PAC, behavioral health, home and community-based services, and other provider settings; and
- F. Certain general principles around interoperability:
 - Provide Patients Access to their Own Electronic Health Information
 - Promote Trusted Health Information Exchange (e.g., participation in Trusted HIE network, require use of the HL7 Admission/Discharge/Transfer standard in the ONC ISA (Interoperability Standards Advisory)
 - Adopt Leading Health IT Standards and Pilot Emerging Standards (e.g., pilot FHIR-APIs, exchange new classes of interoperable data (e.g., use USCDI for psycho-social data)

HCA Comments on Section XI and Section XII

Washington State agrees with the CMS conclusion that, “despite the need for functionality to support better care coordination, discharge planning, and timely transfer of essential health information, interoperability by certain health care providers such as long-term and PAC, behavioral health, and home and community-based services continues to lag behind acute care providers.”

- A. Potential strategies for advancing interoperability across care settings.** In response to the CMS request for comments on potential strategies for advancing interoperability across care settings to inform future rulemaking activity, HCA urges CMS to:
 - i. Include in the USCDI standardized and interoperable functional status content included in Medicare post-acute acute care (skilled nursing facility, home health agency, LTC hospitals, and in-patient rehabilitation facilities) and Medicaid nursing facility required patient assessments.
 - ii. Encourage hospitals, physicians, Medicare PAC providers and Medicaid nursing facilities to incorporate the standardized and interoperable functional status data elements into CCDs on behalf of patients who receive services in the identified Medicare PAC and Medicaid nursing facilities settings. HCA is concerned about “requiring” physicians and hospitals to collect and electronically exchange a subset of the identified PAC patient assessment data elements as these data elements may not always be pertinent to each patient’s hospital/physician encounter.

- iii. Support the interoperable content and FHIR-based API specifications emerging from the Gravity Project for social determinants of health (SDOH) data elements, integrate these interoperable data elements in the USCDI, and encourage their use.
- iv. Collaborate with SAMHSA and ONC to link the SAMHSA required TEDS data elements with accepted HIT vocabulary standards and integrate these interoperable data elements in the USCDI, and encourage the use of these data elements in SAMHSA reporting.
- v. Collaborate with SAMHSA, ONC, the private sector, and state programs to identify functional status domains and data elements applicable to persons with (i) MH and SUD conditions and (ii) intellectual/developmental disabilities, link these data elements with accepted HIT vocabulary standards, integrate these interoperable data elements in the USCDI, and encourage their use.
- vi. Collaborate with SAMHSA and ONC to encourage the set aside of a minimum percentage of SAMHSA Block Grant funds to support investments for the adoption and use of interoperable and certified health IT.
- vii. Collaborate with SAMHSA to modify 42 CFR Part 2 to align with HIPAA to support health information exchange across the care continuum.

B. How HHS can more broadly incentivize the adoption of interoperable health IT systems and use of interoperable data.

C. Ways to test promoting interoperability across the health care spectrum through CMMI models.

D. Policy strategies HHS could adopt to deliver financial support for technology adoption and use in these settings

- i. HCA applauds CMS' stated plans to use CMMI authority under section 1115A of the Act to test ways to promote and advance interoperability across the care continuum and in innovative payment and service delivery models to reduce program expenditures, and include tests of emerging SDOH standards and technology-enabled patient engagement platforms.
- ii. HCA urges CMS to implement a competitive grant program that could be awarded to state Medicaid agencies to test interoperable health information exchange, access, and use with and by behavioral health providers.
 - HCA recommends that CMS focus a new model program on adolescents and young adults with SUDs.
 - Behaviors acquired during this pivotal period often extend into adulthood resulting in lower incomes, higher unemployment rates, and negative physical and mental health outcomes. (<https://ssrc-static.s3.amazonaws.com/moa/YD%20by%20CD%20FINAL%202017.pdf>)
 - Drug use at an early age is an important predictor of development of a substance use disorder later. The majority of those who have a substance use disorder started using before age 18 and developed their disorder by age 20.
 - Of previously incarcerated youths, more than 90% of males and nearly 80% of females had a substance use disorder at some point in their lifetime [<https://www.drugabuse.gov/news-events/news-releases/2016/03/substance-use-disorders-extremely-common-among-previously-incarcerated-youth>]
 - Daily marijuana use has been steadily increasing in prevalence among young adults over the past decade, reaching an all-time high in non-college young adults

- to nearly three times that of their college peers
[\[https://www.drugabuse.gov/related-topics/college-age-young-adults\]](https://www.drugabuse.gov/related-topics/college-age-young-adults)
 - Early use of drugs increases a person's chances of becoming addicted
[\[https://www.drugabuse.gov/publications/drugs-brains-behavior-science-addiction/preventing-drug-misuse-addiction-best-strategy\]](https://www.drugabuse.gov/publications/drugs-brains-behavior-science-addiction/preventing-drug-misuse-addiction-best-strategy)
 - Suicide is the third leading cause of death for youth between the ages of 10 and 24
[\[https://www.cdc.gov/healthcommunication/toolstemplates/entertainmented/tips/suicideyouth.html\]](https://www.cdc.gov/healthcommunication/toolstemplates/entertainmented/tips/suicideyouth.html)
 - Washington State data from the Healthy Youth Survey (published in May 2019) show a high and increasing number of Washington youth reported feeling so sad or hopeless they stopped a usual activity or seriously considered suicide in the past year. For example, based on statewide rates, a typical 10th grade classroom of 29 students would include about: (i) 12 students who have felt sad or hopeless for two weeks or longer in the past year and (ii) three students who attempted suicide in the past year
[\[https://content.govdelivery.com/accounts/WADOH/bulletins/240697e\]](https://content.govdelivery.com/accounts/WADOH/bulletins/240697e)
 - SDOH data (e.g., housing, nutrition, work/educational stability) can affect health and health care expenditures and drive as much as 80 percent of population health outcomes
 - In 2015, more than 12% of people between the ages of 16-24 were neither in school nor working. (Furlong, Andy (2013). Youth Studies: An Introduction. USA: Routledge. pp. 48–49. ISBN 978-0-415-56476-2)
 - Washington has the fifth highest prevalence of homelessness in the nation.
 - At least 13,000 young people, ages 12 through 24, live on the street or in unsafe or unstable housing situations, and are on their own, without a parent or guardian.
 - 23 percent of youth and young adults exiting behavioral health inpatient treatment experienced homelessness in a single year
[\[http://www.commerce.wa.gov/wp-content/uploads/2013/01/COMMERCE-Homelessness-2018.pdf\]](http://www.commerce.wa.gov/wp-content/uploads/2013/01/COMMERCE-Homelessness-2018.pdf)
 - Costly services such as emergency rooms, crisis response and public safety systems are used at a higher rate by homeless individuals.
- HCA recommends that the competitive grant program:
 - Be modeled after the CMMI Integrated Care for Kids Model (InCK) Model and require states to partner with a qualifying Lead Organization (e.g., payer or provider).
 - Require a focus on adolescents and young adults with SUDs.
 - Require States in partnership with a Lead Organization to:
 - identify a targeted geographic area in which the program would be implemented, a comparable geographic area that would allow comparisons and require that the entire target population in the targeted geographic area be included in the interventions implemented in the program; and
 - Include implementation of evidence-based practices applicable to the target population.

- Include a focus on interoperable information sharing with and by behavioral health providers, other service providers (e.g., physical health providers, schools, justice system, social service providers, supported employment/ housing providers), individuals, and family care givers.
- Include incentives to support the adoption, and use of interoperable and certified health IT by behavioral health providers to improve the quality and coordination of care through the electronic documentation and exchange of health information. HCA notes that making available incentives to support the adoption and use of certified EHRs/health IT by behavioral health providers is consistent with Section 6001 of the Support ACT (“Testing of incentive payments for behavioral health providers for adoption and use of certified electronic health record technology”).
- Require information exchange in compliance with:
 - current and emerging federal health information exchange standards, including using USCDI, emerging SDOH data, and FHIR-based APIs; and
 - federal and state privacy and security laws (including 42 CFR Part 2)
- Measure changes in utilization and costs of ER, hospitalization, and incarceration (including recidivism); and
- Identify, implement, and incent measures related to:
 - interoperable HIE (e.g., measures related to timeliness of HIE, use of FHIR-based APIs)
 - improving the health and functional status of target population.

E. Measure concepts that assess interoperability. HCA supports CMMI promoting and/or incentivizing the use of health IT and demonstrated commitment to interoperability among model participants as part of the design, testing as well as a condition of participation in CMMI payment and service delivery models. Possible strategies could include a prospective payment tied to performance on interoperability metrics. The degree of risk tied to interoperability metrics should be adjusted depending on if model participants are large provider systems, small provider practice, or rural health system.

In addition, HCA recommends that future CMMI payment and service delivery model programs (e.g., one that includes incentives for interoperable information sharing with and by BH care providers targeting adolescents and young adults) include a planning phase during which measures related to changes in costs and use of high cost settings of care, interoperable HIE, changes to the health and functional status of the target population, and other measures would be identified. We recommend that grantees be encouraged to re-use, align, and/or improve existing measures. HCA recommends that planning phase support the identification of measures that focus on the:

- interoperable content emerging from the Gravity Project for social determinants of health (SDOH) data elements;
- data element specifications emerging from the collaborations (suggested elsewhere in the Washington State HCA comments) between SAMHSA, ONC, the private sector, and state programs that identify the functional status domains and data elements applicable to persons with MH and SUD conditions and link these data elements to health IT content standards; and
- health information exchange, including timeliness of HIE and use of FHIR-based APIs.

- F. Incentives for BH provider adoption and use of certified Health IT/EHRs.** HCA recommends CMS create an incentive program to encourage the adoption and use of interoperable and certified health IT/EHRs by behavioral health providers to improve the quality and coordination of care through the electronic documentation and exchange of health information. Such an incentive program:
- could be leveraged in the new /extended CMMI Integrated Care for Kids Model (InCK) Model that focuses on adolescents and young adults with SUDs (see other comments provided by HCA);
 - could support the implementation of many of the tasks required by CMS in the Health IT Plan included the CMS Mental Health Institution for Mental Diseases (IMD) Waiver; and
 - would be consistent with Section 6001 of the Support Act (“Testing of incentive payments for behavioral health providers for adoption and use of certified electronic health record technology”).
- G. Strategy, guidance, and grant program on the interoperable exchange of information related to Child Abuse Prevention and Treatment Act (CAPTA).** HCA urges HHS to develop a strategy, provide guidance, and implement a grant program on the interoperable exchange of information needed to ensure the well-being of pregnant and post-partum women, infants and young children who may be affected by substance abuse/exposure, withdrawal symptoms, or Fetal Alcohol Spectrum Disorder (FASD). HCA recommendations support implementation of the Child Abuse Prevention and Treatment Act (CAPTA) and amendments to CAPTA made by Section 7065 of the Substance Use–Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (the Support Act).

HCA recommends, consistent with the provisions of CAPTA, that:

- 1. HHS develop a strategy and guidance/technical assistance regarding pregnant and post-partum women, infants and young children who may be affected by substance abuse/exposure, withdrawal symptoms, or FASD.**
 - HCA recommends that HHS develop a strategy and guidance/technical assistance by convening: federal partners (e.g., ACF, CMS, SAMHSA, CDC, NIDA, HRSA, ONC), state and local agencies (e.g., Medicaid, CHIP Agencies, public health organizations, child welfare and protective service agencies, criminal justice organizations), health and social providers (e.g., acute care hospitals; primary care, mental health, substance abuse, and developmental disabilities providers; and domestic violence service agencies), and representatives from tribal organizations and tribal health care providers;
 - The strategy/guidance would:
 - Identify evidence based /emerging best practices for pregnant and post-partum women, infants and young children who may be affected by substance abuse/exposure, withdrawal symptoms, or FASD,
 - Address service delivery including:
 - screening tools;
 - assessment;
 - needed medical, behavioral, developmental, and social support treatment and services;

- development and content of plans of safe care; and
 - parent and caregiver engagement;
- Address reporting, investigating, and prosecuting cases involving substance abuse/ exposure, withdrawal symptoms, or FASD; and
- Address interstate and intrastate information exchange (including interoperable exchange) needed to treat, report, and otherwise respond to substance abuse/exposure, withdrawal symptoms, or FASD with respect to pregnant women, mothers or infants;
- Consider the clinical and administrative workflows associated with alternative use cases that take into account the content needed for:
 - prevention, assessment, and treatment; and
 - reporting, investigation, and prosecution
- Identify the roles of: (i) health and social service providers/organizations, (ii) pregnant women/ mothers/caregivers, and (iii) child welfare and protective agencies in the:
 - creation, exchange and implementation of plans of safe care; and
 - reporting, investigating , and prosecution of cases involving substance abuse/exposure, withdrawal symptoms, or FASD.
- Identify available (accepted and emerging) content, privacy, and FHIR-based exchange standards, and gaps in standards and steps to address these gaps to support the interoperable exchange of:
 - plans of safe care; and
 - health and administrative data needed for reporting, investigating, and prosecuting cases involving substance abuse/exposure, withdrawal symptoms, or FASD.

2. HHS implement a grant program to advance the collaboration, coordination and information exchange regarding pregnant and post-partum women, infants and young children who may be affected by substance abuse/exposure, withdrawal symptoms, or FASD.

HCA recommends that CMS implement the grant program authorized in CAPTA as amended by Section 7065 of the Support Act. Section 7065 of the Support Act modified CAPTA to permit the Secretary of HHS to “make grants to States for the purpose of assisting child welfare agencies, social services agencies, substance use disorder treatment agencies, hospitals with labor and delivery units, medical staff, public health and mental health agencies, and maternal and child health agencies to facilitate collaboration in developing, updating, implementing, and monitoring plans of safe care ...”.

HCA recommends that the grant program: (i) take into account the strategy and guidance/technical assistance developed through the convening of federal, state/local, and provider stakeholders, and (ii) include:

- Best practices for:
 - service delivery to pregnant and post-partum women, infants and young children who may be affected by substance abuse/exposure, withdrawal symptoms, or FASD;

- reporting, investigating, and prosecution, investigating, and prosecution of cases involving substance abuse/ exposure, withdrawal symptoms, or FASD;
- interstate and intrastate information exchange (including interoperable exchange)
- Clinical and administrative workflows associated with and the roles of: (i) health and social service providers/organizations, (ii) pregnant women/ mothers/caregivers, and (iii) child welfare and protective agencies in:
 - prevention, assessment, and treatment; and
 - reporting, investigation, and prosecution
- Use of accepted /emerging health IT standards related to content, privacy and FHIR-based exchange for the interoperable exchange of:
 - plans of safe care; and
 - health and administrative data needed for reporting, investigating, and prosecuting cases involving substance abuse/exposure, withdrawal symptoms, or FASD.

H. General principles around interoperability.

HCA commends CMS on seeking to establish general principles around interoperability within Innovation Center models for integration into new models, through provisions in model participation agreements or other governing documents. HCA believes that the use of health IT and health information exchange is essential for transforming service delivery and payment across the health care continuum. Further while health IT and health information exchange is essential, as noted in the CMS NPRM and the Washington State HCA comments, adoption and use of interoperable and certified health IT is not ubiquitous across the care continuum. HCA supports the idea of establishing general principles around interoperability within Innovation Center models that would be integrated into new models (e.g., through provisions in model participation agreements or other governing documents).

1. HCA supports the general principle of providing patients access to their own electronic health information.
2. HCA also supports the principle that models support the use of technology (including but not limited to APIs) to enable providers to make available (with the patient’s authorization) PHI to third party developers.
3. HCA appreciates the vision establish by ONC regarding the “Trusted Information Exchange Network” and recognizes the critical roles/functions that such networks will play in the future. However, the Washington State HCA is concerned that participation in Trusted HIE Networks is not yet possible. Thus, we believe that to include requirements related to exchange via Trusted Exchange Networks in Innovation Center payment and service delivery models would be premature at this time, and could effectively prevent near/mid-term testing of payment and service delivery models that could improve the quality and cost-effectiveness of care.
4. HCA supports the general principle that Model participants be required to participate in electronic alerting via one of the standards described in the ONC Interoperability Standards Advisory (ISA): including the Admission, Discharge, and Transfer (ADT) if the use of the standard is relevant to the model being tested.

5. HCA supports the general principle that Model participants and their health IT vendors adopt leading health IT standards and pilot emerging standards (e.g., pilot FHIR-APIs, exchange new classes of interoperable data (e.g., use USCDI for psycho-social data) to improve interoperability for care management, quality reporting or other priority use cases.

Section XIII: Request for Information on Patient Matching

In section XIII, CMS solicits comment regarding an approach to addressing patient matching concerns. We agree that patient matching is a significant concern and support CMS in taking a broad-view federal approach on this topic in conjunction with the request from the Office of the National Coordinator (ONC). We appreciate the opportunity to provide comment.

HCA comments:

- A consistent patient matching strategy is foundational to the goals outlined in this rule. We urge CMS to accelerate and resolve the patient matching strategy prior to establishing rules regarding volume and speed of data exchange.
- We support CMS in considering and exploring modern patient matching algorithms. We consider this to be a superior approach to creating a Universal Patient Identifier (UPI) or the CMS-wide identifier mentioned later in this section. While there could be potential in a UPI, a UPI does not support more advanced matching procedures that can incorporate sparse historical data and additional data points where available.
- As mentioned in the rule, there is a significant lack of information available on the success rates and accuracy of patient matching. We support creating a transparent and consistent measurement strategy that allows for improving patient matching software and algorithms without enforcing specific software or algorithms. This should include a use-case driven repository of evaluation results such as accuracy, automation vs. manual effort, and time performance.
- A consistent patient matching strategy requires a significant look at how false positives and false negatives would be managed and remediated throughout the system. This type of structure must be built into the system early in order to limit the impacts of later discovery.

CMS contemplates their role in prescribing specific patient matching algorithms or software. Comments:

- We support a CMS role in ongoing development of best practices on patient matching algorithms, publishing the criteria, method, rules, accuracy and other attributes related to the algorithm, and encouraging the use of these algorithms.
- We support a CMS role in maintaining a list of software that meets the best practices through a transparent approach such as that used by Office of the National Coordinator's (ONC) Certified Health IT Product List. CMS could enhance or encourage certain algorithms or software by creating a comprehensive testing platform that shows how software vendors have met the specified CMS criteria, publishing results in a standardized, public, and understandable fashion.

CMS contemplates creating a CMS-wide identifier and advancing standardized data elements, such as the USCDI, across HHS systems for matching purposes.

HCA comments:

- We believe there is significant work needed to allow many HIPAA covered entities to exchange data related to the USCDI in a convenient and scalable manner. We encourage CMS to explore reduction of provider and administrative burden in support of a consistent patient matching strategy, which may be separate from the expanded data set of the USCDI.
- We recommend the standard usage of ‘entity clustering’ identification to link records together for operational effectiveness. An extension of this would be the ability to have multiple clustering identifiers based on different matching methods.

CMS discusses the addition of verifying data sources for identity proofing within data sources generated from CMS and overseen-entities.

HCA comments:

- There are benefits to additional verification sources, but complications arise when looking at some of the populations served by the State. Verifying data requires human resources to compare machine matches with human verification and the creation of machine learning data sets, often requiring verification from the originating source of data.
- State and federal laws complicate the ability to collect certain identity verification sources, such as biometric data. We urge CMS to convene stakeholders from State and Tribal governments, as well as patient advocacy groups, on how to enhance patient identification throughout our respective programs while still maintaining trust and confidentiality for members, patients, and citizens.
- We recommend that CMS and HHS create and publish guidance on how sensitive data such as biometric data could be collected and shared to support these efforts, including the identification of federal rules that relate to the collection of data at the point of program eligibility determination.
- This guidance should also include an analysis of State privacy laws that correspond to the collection of sensitive data and recommendations for how States may review existing privacy laws aligning with federal law while still maintaining trust and confidentiality for members, patients, and citizens.

Last, CMS asks to what extent patient-generated data could complement patient-matching.

HCA comments:

- The amount of patient-generated data is vast, with the quality and usefulness varying significantly by source and collection method. Many Washington State data sources are not equipped to incorporate this type of data, and would require an extensive investment in both human and technical processes to accommodate. Without a consistent federal strategy, appropriate resources (time and money) to implement, Washington and other states may focus investments on patient-generated data in a way that does not support interstate or nationwide patient-matching goals. We urge CMS to develop a nationwide strategy regarding areas of focus for patient-generated data, and provide appropriate resources (time and money) for State implementation.
- We support the concept of utilizing patient portal technology to remediate patient matching errors. Supporting populations in accessing, understanding, and using patient portal technology

to verify or invalidate patient matching would require additional staff and infrastructure to maintain and support our clients.

- We would also need to consider how incorrect matches, otherwise called false positives, could be removed from past records and prevented from future matchings. This could be supported through patient portals which allow for remediation, but would otherwise require additional manual intervention to resolve.

HCA wants to thank CMS for taking our comments into consideration for the implementation of these important provisions to support the sharing of health information.

Sincerely,

MaryAnne Lindeblad

Medicaid Director