THE AMERICAN
HEALTH QUALITY
A S S O C I A T I O N

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Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-9115-P
P.O. Box 8016
Baltimore, MD 21244–8013

Dear Administrator Verma,

Thank you for the opportunity to comment on proposed rule (CMS-9115-P) Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans in the Federally-Facilitated Exchanges and Health Care Providers.

Our organization, the American Health Quality Association (AHQA), represents the Quality Innovation Network-Quality Improvement Organizations (QIN-QIOs) and their quality improvement partners throughout the United States, Puerto Rico, the Virgin Islands, and the outer Pacific Islands. Our association's goal is to make health care better, safer, and available at a lower cost.

As organizations charged with working with providers, beneficiaries, families, and stakeholders to improve health quality practice and delivery, QIN-QIOs are keenly interested in the advancement and alignment of health IT across the healthcare continuum.

Below are our comments regarding the proposed rule.

CHALLENGES AND BARRIERS TO INTEROPERABILITY
Patient Identifier and Interoperability
Patient identification and interoperability is critically important to maintaining and advancing our healthcare system. We recognize the careful consideration that HHS must take when determining the appropriate identifier for patients and propose the following elements be considered when exploring patient identification and interoperability:

- What are the common elements and what is the standard for matching (HL7)?
    - HL7 has been a standard for data sharing (i.e. Interfaces between EHRs and lab companies, practice management systems, registry reporting, etc.)
- Patient data fields are self-reported (e.g. name, date of birth, address, gender) and can lead to data entry inconsistencies

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- o Name changes - staff and patient must have ongoing interactions to update these data elements; could lead to staff and patient burden
- o Address change updates - staff and patient must have ongoing interactions to update these data elements; could lead to staff and patient burden
- o Patient portal entry of demo
- o Staff entry of demo

We applaud ONC's support and understanding of the critical need to standardize matching for patients to ensure interoperability and integration across EHR and/or HIE systems. We would appreciate more clarification around the "private sector" involved in patient matching, specifically; does it encompass multi-stakeholder participation (Health Systems, patients, providers, insurers, EHR vendors, HIE vendors, Pharmacies, LTC, SNF, etc.)?

Lack of Standardization
We agree that a lack of standardization inhibits the successful exchange of health information without additional effort on the part of the end user. We are concerned that setting a standardization of data requirements for vendors will result in additional charges to providers/health systems. Similarly, we question whether any additional technology would be required (to support APIs) for providers. Any financial burden for these standardizations and technological additions should be borne by the vendors, not the providers. Additionally, data originating from these platforms will need to be able to be vetted, sorted and imported into EHRs in usable formats; providers need to be able to select the data to import/include in their systems; as desired. Lastly, there will need to be extensive education for providers, staff, and patients on APIs and how to utilize them to support increased interoperability.

Information Blocking
The practice of health information blocking is detrimental to interoperability. CMS has already been combatting this issue by making the prevention of information blocking a required measure that an eligible Merit-based Incentive Payment System (MIPS) clinician must attest "yes" to in order to receive any points in the promoting interoperability category.

- This is a great first step to limit the amount of information blocking as it deters clinicians from blocking health information because they will not be able to receive the maximum amount of Medicare payment adjustment without attesting "yes" to the prevention of information blocking.
- Taking this requirement one step further by then publicly reporting those who attest "no" to the prevention of information blocking is a good idea. Placing these public postings on the same website where potential patients can view MIPS scores to identify clinicians with whom they might want to establish care will work well if patients are educated about health information blocking.

AHQA is concerned about the number of clinicians that do not attest for promoting interoperability if they know that they will receive zero points in the promoting interoperability category if they attest "no" to the prevention of information blocking. Additionally:

- Based on this rule, those who do not attest for the promoting interoperability section and, therefore, do not attest to the prevention of information blocking measure, will not have anything listed on their physician compare profile because CMS will not know whether or not that clinician prevented information blocking.
- Clinicians who practice information blocking likely aren't actively reporting it. As the number of MIPS points needed to avoid a negative payment adjustment rises, this will not be an issue, but for 2019, clinicians do not need to report for the promoting interoperability category to avoid a negative payment adjustment.
- There might be some clinicians who choose to attest "yes" to the prevention of information blocking though they are not practicing that way. The attestation of prevention of information blocking within MIPS may need to be re-worked in order to more accurately describe the clinician population's status on information blocking.

We would also like additional clarification around the following items:

- How can it be confirmed that all patient data is being shared by a provider/health system?
- Can providers/health systems charge patients for release of their information?

Lack of Adoption/Use of CEHRT in PAC
We agree that PAC facilities are critical in the care of patients' post-hospital discharge and can be a determining step in the health progress for those patients. We propose the following elements be considered when exploring adoption/use of CEHRT in PAC:

- Will there be a standard format of assessment; that is consumable by EHRs?
- Will there be penalties for PACs who are not utilizing CEHRT and/or exchanging data? If none, would assessing payment adjustments encourage adoption/use?
- Determine how HIEs can be utilized by these PACs for adoption/spread of interoperability.
- Educate the facilities on importance of interoperability and data integration for their patients and providers/health systems.

Privacy/HIPAA
Patient education and understanding of interoperability are necessary as some interoperability solutions/HIEs require patients to agree to opt-in or opt-out of participating in data sharing. While patients may sign waivers for their providers to share data with outside parties (i.e. Health plans, other providers, ancillary services, etc.), they may not fully understand what is being shared. We anticipate that patients may feel their privacy has been violated by not having a clear understanding of interoperability.

PROVIDER DIGITAL CONTACT INFORMATION

Utilizing the National Plan & Provider Enumeration System (NPPES) is an efficient way to use an existing system to fulfill the Congressional requirement to establish a digital contact information system that can support the sharing of information.

- A deficiency mentioned in the proposed rule is that many providers have not submitted provider digital contact information. One solution is to add this as a measure within MIPS. This could serve to gain additional contact information for clinicians while simultaneously increasing interoperability. Adding this to the MIPS requirements would also help keep this information up to date as clinicians would ideally go in to the NPPES to update their information annually.
- While the suggestion of publicly reporting those providers, who do not have digital contact information included in the NPPES system is a good start, AHQA does not think it would be very meaningful to many providers.

One major difficulty that clinicians face is the lack of interoperability between electronic health record technologies. This makes the health information exchange measures of MIPS difficult to achieve or excel in.

- The provider digital contact information index can help bridge the interoperability gap and possibly open some new opportunities for competition to create interoperability features within electronic health record technologies that already exist.
- One way this could be achieved is by creating a promoting interoperability tracking system within NPPES. The promoting interoperability measure data can be aggregated between systems by adding the numerators and denominators for each system a clinician uses. If the NPPES allows clinicians to have increased interoperability and allows clinicians to engage in "health information exchange" it could be worthwhile to have a tracking system within NPPES that recognizes when a clinician uses the secure exchange system. For example, if a provider refers a patient and sends a summary of care then the tracking system could give the provider a numerator and denominator that corresponds with the promoting interoperability measure, "Support Electronic Referral Loops by Sending Health Information." When a clinician goes to report for MIPS they would then add the numbers tracked within NPPES and the numbers found in the MIPS dashboard within their certified electronic health record technology (CEHRT) to aggregate their data. This would allow clinicians who often refer patients to clinicians who do not operate on their CEHRT and therefore lack interoperability.

REVISIONS TO THE CONDITIONS OF PARTICIPATION FOR HOSPITALS AND CRITICAL ACCESS HOSPITALS (CAHs)

We applaud CMS for calling out electronic patient event health information exchange as an effective and scalable tool that can improve care coordination across setting. A significant amount of current coordination of care work is spent trying to find more reliable and efficient ways to access and communicate information; this would help to reduce some of that burden. We also appreciate the proposed improvements to medication reconciliation.

REQUEST FOR INFORMATION ON PATIENT ACCESS THROUGH APIs
<u>Medicare Blue Button 2.0</u>
We applaud CMS' commitment to advancing interoperability, putting patients at the center of their health care, and ensuring they have simple and easy access, without special effort, to their health information. We suggest CMS consider adopting a standard format for claims data so patients can share this with health care providers to ensure providers have access to a patient's history. This will also help to:

- Reduce duplication of testing.
- Provide a more longitudinal view of a patient's health.
- Allow for timely access to patient information.

<u>Expanding Availability of Health Information</u>
We strongly support providers having access to data to help determine patients' adherence to medications, services, and recommended treatments. We also believe this has the potential to increase patient engagement in their treatment; potentially reducing risks of serious health situations, as well as:

- Identify/address social determinant issues and suggest opportunities for assistance.
- Reduce duplication in patient care.
- Provide a higher quality of care delivered to the patient.
- Ensure consistency across their patient base, especially dual eligible beneficiaries, by Including all CMS programs.

We would also appreciate additional clarification around the following items:

- How will this data be sorted in the API? Will it be easily identifiable for the patient being treated?
- How frequently will data be updated? Will there be automatic data feed updates to the 3rd party vendors to consistently retrieve data without patient involvement?

<u>Open API Proposal for MA, Medicaid, CHIP, and QHP Issuers in FFEs</u>
We support the concept of requiring MA organizations, state Medicaid FFS programs, Medicaid managed care plans, CHIP FFS programs, CHIP managed care entities, and QHP issuers in FFEs (excluding issuers of SADPs) to implement, test, and monitor an openly-published API that is accessible to third-party applications and developers. We believe it will be a positive outcome for patients to have access to formulary/coverage information available in order to make informed decisions as well as increase in patient involvement in their health. We also encourage CMS to consider the following when refining this proposal:

- This proposal assumes all CMS payers, except CHIP managed care, will use the same open API; how often will they be required to monitor the API?

- How will lab data results be collected? Will there be interfaces with lab vendors? Will data be pulled from a repository? How quickly will results be updated? Is it possible the patient will have results so quickly that providers may not have had an opportunity to discuss them with the patient? If so, this could cause some patient anxiety, increased calls to providers, and be burdensome to practices.
- The timeliness of data will also depend on outside sources (i.e. how quickly a claim is filed, how quickly health information is shared/received.)
- Will data, regardless of payor, be accessible through the same technology; smartphones, tablets, laptops, etc.? Some payor sections are explicit about the technologies that can be used while others refer to common technologies and only list a few (page 7630 under section 3 vs page 7629 section 2). Depending on the technologies permitted, there could be concerns about security and how data can/will be protected.
- API and availability to provider - how will updates be sent to the provider through the API once the enrollee authorizes release?
- Section B:
    - If CMS allows use of updated standards without amendment to regulations, it will need to ensure these standard changes do not result in data not being able to be shared/imported into systems.
- Section C:
    - How often will patient claims and encounter data be available for retrieval by 3rd parties? Will there be an automatic feed to 3rd parties via API? What burden may be placed on providers having to have data available to payers (through contract negotiations) within a timeframe. CMS will need to consider time for encounter finalization (i.e. waiting on lab/test results). If they have to amend the encounter to incorporate test results, it creates additional work on providers to do so. What if "incomplete" encounter data can be shared, but clearly noted as "incomplete" in API? 1 business day may not allow time for all data to be incorporated into the visit information. CMS will need to consider an average for test results to be received/reviewed by the provider and communicated to patients.
    - Provider Directory Data: It will be beneficial for patients to know who is available to treat them and how to contact provider offices. If the data QHP FFE collects for the directory is accurate and timely, it would not be necessary to introduce burden to conform to other standards.
    - Clinical Data including Lab Results: We believe that the data will be dependent on the timeliness of providers submission. One business day once received seems as real-time as possible.
    - Drug benefit/directory/formulary: We believe that not having formulary info for MA plans updated in a defined timeframe lead to patients not having what they need for informed decision making. We would like clarification as to why there are timeframes for MCD and CHIP but not MA plans.
- Section D:

- o How often will published API technical documents be reviewed/updated and shared? Will this offer a test area for 3rd party vendors to test their formatting to ensure data structure is correct and complies with formatting standards?
- Section E:
  - o What protocols will be in place if an issue is found during testing/monitoring? How will patients/3rd party vendors be alerted that the system is not working properly? How will they be alerted once issues have been resolved?
- Section F:
  - o We suggest ensuring privacy/security on "smart technologies" will not compromise patients' health data.
- Section G:
  - o If 3rd party has been noted as violating privacy rules for collected data, will payers be able to deny 3rd parties' access "across the board for all patient queries and all payers" (i.e. dual eligible beneficiaries)? Will patients have access to "terminate" the 3rd party's access to their health data on the payer portal?
- Section H:
  - o We suggest CMS offer means to convey information other than in writing. For example, provide audio for those who cannot read or see well, because the target audiences could be elderly patients or patients with disabilities.
- Section I:
  - o We encourage CMS to consider if there any cases where dental data might be useful for other healthcare providers to treat patients.
- Section J:
  - o We are concerned about the proposal for the different plans having different start dates. We are concerned that this will cause confusion, especially for dual eligible beneficiaries because the patient may not have access to all the plans' data.
- Section K:
  - o To fully realize the benefit of the health information exchange, providers having access to full patient data will be crucial and the timeliness of the data will impact how the provider can care for the patient.
- How will data discrepancies be addressed and how will data updates/deletions/changes be noted in these APIs? Will there be a historical log of data that was shared? Additionally, are there any concerns about potential patient harm if a provider makes a decision about patient health based on data provided through API, but that data was wrong, inaccurate or changed from updated information shared initially?

REQUEST FOR INFORMATION ON POLICIES TO IMPROVE PATIENT MATCHING

We agree that the lack of a UPI inhibits interoperability efforts because, without a unique identifier for each patient, the safe and secure electronic exchange of health information is constrained due to the difficulty ensuring that the relevant records are all for the same patient.

Our responses to the questions posed in the RFI are included below.

1. Should CMS require Medicare FFS, MA Plans, Medicaid FFS, Medicaid managed care plans (MCOs, PIHPs, and PAHPs), CHIP FFS, CHIP managed care entities, and QHP issuers in FFEs (not including SADP issuers), use a patient matching algorithm with a proven success rate of a certain percentage where the algorithm and real world processes associated with the algorithm used are validated by HHS or a 3rd party?
   - Yes. If interoperability is to be realized for MCR/MCD beneficiaries, there must be an industry standard algorithm to match patients and their health data from the various sources. CMS must create an industry standard to be adopted by all involved in interoperability, including EHRs, insurance companies, lab reporting systems, registries, etc.
2. Should CMS require Medicare FFS, the MA Plans, Medicaid FFS, Medicaid managed care plans, CHIP FFS, CHIP managed care entities, and QHP issuers in FFEs to use a particular patient matching software solution with a proven success rate of a certain percentage validated by HHS or a 3rd party?
   - If there is a standardized, unilateral solution implemented, there is no room for varying interpretations by multiple vendors on the requirements/data needed for interoperability.
3. Should CMS expand the recent Medicare ID card efforts by requiring a CMS-wide identifier which is used for all beneficiaries and enrollees in health care programs under CMS administration and authority, specifically by requiring any or all of the following:
   - That MA organizations, Part D prescription drug plan sponsors, entities offering cost plans under section 1876 of the Act, and other Medicare health plans use the Medicare ID in their plan administration.
   - That State Medicaid and CHIP agencies in their FFS or managed care programs use the Medicare ID for dual eligible individuals when feasible.
   - That QHP issuers in FFEs use the Medicare ID for their enrollees in the administration of their plans.
       - Yes, including an additional identifier in an already issued CMS health insurance patient identifier may encourage the spread, adoption and implementation across the care continuum as this information (i.e. Medicare #s) is currently used in patient care and included in some data sharing.
       - One thing to consider would be the programming required for health IT vendors to accommodate this new identifier; time to program, implement and upgrade practices across the US (insurance entry data fields, standard data fields (CCD, HL7) where this data is already being sent in a formatted file.
4. Should CMS advance more standardized data elements across all appropriate programs for matching purposes, perhaps leveraging the USCDI proposed by ONC for HHS adoption at 45 CFR 170.213?

- Yes, data standardization will provide a defined requirement for development/data sharing and will not leave room for interpretation.

5. Should CMS complement CMS data and plan data in Medicaid managed care plans (MCOs, PIHPs, and PAHPs), CHIP managed care entities, MA Plans, and QHP issuers in an FFE (not including SADP issuers) with one or more verifying data sources for identity proofing? What potential data source should be considered? What are possible restrictions or limitations to accessing such information?

    - CMS could potentially consider a national registry.

6. Should CMS support connecting EHRs to other complementary verifying data sources for identity proofing? What potential data source should be considered? What are possible restrictions or limitations to accessing such information?

    - Yes, implementation of a national repository to validate.
        - What data is CMS proposing will be validated?
        - If the EHR validates or finds discrepancy, how are/will those discrepancies be able to update the HER? Will they use a standardized format to update or will there be manual changes in the EHR? Interface- unidirectional and bidirectional? CMS needs to consider the cost vendors may charge to the practice, health system, ancillary services, etc. to implement this verification. Will it be embedded into application or contain a hyperlink within the application? What would be the time required for the vendor to program, test, and upgrade the client base (restrictions/limitations)?

7. To what extent should patient-generated data complement the patient-matching efforts?

    - What does CMS consider patient-generated data to compliment patient matching?
        - Self-monitoring (BP, Blood glucose, activity, food, etc.)
        - Name, date of birth, address

Thank you for the opportunity to comment above on the proposed rule. We believe our observations, comments, and recommendations are aligned with and in support of CMS, as well as the long history and demonstrated successes of the QIN-QIOs in partnering with HHS to achieve substantive improvement in health care quality.

Regards,

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