

STATE OF WASHINGTON

### DEPARTMENT OF HEALTH

PO Box 47890 • Olympia, Washington 98504-7890 Tel: 360-236-4030 • TTY Relay: 800-833-6384

June 10, 2025

The Honorable Dr. Mehmet Oz, MD Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS), Attention: CMS-9115-P, P.O. Box 8016, Baltimore, MD 21244-8016.

#### Re: Comments on Propose Rule: Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2026 Rates; Requirements for Quality Programs; and Other Policy Changes

The Washington State Department of Health (DOH) appreciates the opportunity to comment on the proposed rule, "Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2026 Rates; Requirements for Quality Programs; and Other Policy Changes," printed in the Federal Register on April 30, 2025 (FR Vol 90, No. 82). Public health activities play a critical role in the health of all Americans, including those receiving healthcare coverage from the Centers for Medicare & Medicaid Services (CMS). DOH has many programs that receive and send data to clinical data partners through their health IT systems. This includes immunization records, prescription drug monitoring data, birth data, newborn screening results, cancer registry, syndromic surveillance, electronic case reporting, and electronic lab results. It is vital for public health agencies to exchange data efficiently and effectively with clinical partners. DOH appreciates the Promoting Interoperability Program's role in incentivizing this exchange.

DOH strives to make transacting data with public health as seamless and efficient as possible for health care providers. Our agency leverages the interoperability standards set forth by HHS for public health measures and believes this work has been essential to making public health reporting more efficient for both healthcare providers and public health agencies. DOH has also invested in health information exchange to provide a way for clinical partners to submit data across many programs through one transport method instead of many. Additionally, DOH has partnered with our state Medicaid agency to help promote interoperability, improve health outcomes, drive efficiency, and save money. DOH offers the following comments on the proposed regulations for the Medicare Promoting Interoperability Program:

### Toward Digital Quality Measurement in CMS Quality Programs—Request for Information (Page 18323)

DOH applauds the digital quality measures collaboration between CMS and the Centers for Disease Control and Prevention (CDC). There are often overlapping needs that can put duplicative requirements on our healthcare partners between what CMS needs from a quality perspective and what CDC needs from a surveillance perspective. DOH has been working on an initiative to reuse the quality measure definitions for hypertension and diabetes to provide chronic disease prevalence surveillance for public health. Specific responses to the questions posed in the RFI outlined below.

Are there specific eCQMs or elements of existing eCQMs that you anticipate presenting particular challenges in specifying in FHIR?

• There are new measures being developed for public health reporting that might not have the required stratifications available. For example, stratification by age groups for reporting aggregate data for respiratory conditions.

What supplementary activities would encourage additional engagement in FHIR testing activities (such as Connectathons) that support the development of current and future IGs to advance adoption and use of FHIR based eCQMs?

• DOH regularly participates in HL7's FHIR-related events including Connect-a-thons, Dev Days, and working group meetings, as well as the HIMSS Interoperability Showcase. We believe these activities improve engagement and support development. DOH recommends CMS and CDC partner on these activities to demonstrate how measures can be shared for both payer quality and public health use cases.

Can you share any experiences or challenges reviewing, implementing, or testing the QI-Core, DEQM, or Bulk FHIR standards, including any experiences or challenges unique to Bulk FHIR Import versus Bulk FHIR Export?

- Access to test servers and relevant test data are often a challenge, especially if you want more than one or two test patients/cases. Ideally, a test server should allow users to select both FHIR version (e.g., R4, R5, 7.0.0, etc) and relevant implementation guides (e.g., Bulk Data Access 2.0.0).
- Use of Bulk FHIR standards for 'data gathering' and using the data sets for evaluating specific measures is not a practice that has been widely adopted yet. This process, when developed, is expected to improve efficiency for periodic reporting of measure reports that specifically pertains to eCQMs. However, when it comes to real-time or near real-time reporting, the combination of bulk data and aggregate reporting (mostly pertaining to dQM for situational awareness) proves challenging and extremely resource intensive in terms of bulk export and measures computation.

What, if any, additional concerns should CMS take into consideration when developing FHIR-based reporting requirements for systems receiving quality data?

- Traditionally CMS has used/requested claims data to evaluate Medicaid/Medicare quality improvement or treatment impact. Yet, claims data doesn't measure the impact of provider treatments or public health approaches on patient health indicators. In order to extract these indicators, there needs to be a standard way in which providers, clinics, and hospitals gather patient data through baseline assessment and/or new patient intake questionnaires. Data gathered from regular visits to clinics/providers is essential to measure the treatment's effectiveness and it is also necessary to gather information from different health care systems as many Medicaid recipients are very mobile or migratory.
- CMS's strategy to advance digital quality measures (dQMs) should take Medicaid into consideration to ensure consistency and scalability across all federal programs. Specifically, CMS should align Medicaid with Medicare and Marketplace efforts in areas such as measure definitions, data standards (e.g., FHIR-based reporting), and infrastructure investments to reduce burden on providers serving dual-eligible and low-income populations. Including Medicaid in the eCQM roadmap will help address health disparities and support states in building interoperable systems that serve all beneficiaries.

#### Proposal To Define the EHR Reporting Period in CY 2026 and Subsequent Years (Page 18355)

DOH supports the proposal to keep the 180-day requirement moving forward now that it has already been established in the last rule changes. DOH would also like to propose providing an exception to eligible hospitals (EH) and eligible providers (EP) when a public health agency (PHA) is unable to onboard them in the year they have to move from validation to production. Given the resource constraints that PHAs are now facing there could be situations where an EH/EP is ready to move to production, but the PHA is unable to get to them in the queue and we do not feel their PH reporting points should be withheld in that circumstance.

#### <u>Proposal To Modify the Public Health and Clinical Data Exchange Objective: Adoption of an</u> <u>Optional Bonus Measure for Public Health Reporting Using the Trusted Exchange Framework</u> <u>and Common Agreement (TEFCA) (Page 18359)</u>

DOH was an early public health adopter of TEFCA. We were successfully able to leverage it to receive electronic case reports from a provider that has a footprint in both WA and OR. Using TEFCA allows this provider to make just one connection to submit electronic case reporting (eCRs) for both states. We are still using this connection in production today. DOH believes it is valuable to incentivize providers to further leverage TEFCA for public health data exchange. However, one concern is that the proposed rule offers 5 bonus points for any of the 3 bonus measures met, but a provider is not allowed to do multiple bonuses. This could dilute the bonus measures section and make it hard for public health to encourage providers to extend beyond the 6 required public health measures to other important public health registries. DOH encourages CMS to consider allowing each bonus measure to provide 5 points vs. only being allowed to get points for one.

#### <u>Request for Information (RFI) Regarding the Query of Prescription Drug Monitoring Program</u> (PDMP) Measure (Page 18371)

Should CMS propose to adopt a performance-based (numerator/denominator) reporting requirement for the Query of PDMP measure? If so, how should the numerator and denominator be defined?

• There is a potential barrier for hospitals and CAHs if performance-based reporting on PDMP queries is adopted. Currently there are three mechanisms for WA State providers to query the PDMP; through the PDMP portal (manual query) or through the integration options, Bamboo Gateway and Washington's Health Information Exchange (HIE). Currently, the health information exchange (HIE) is configured in a way that a facility credential, rather than a provider credential, is reported when a provider queries the PDMP. While we are not sure if hospitals and Critical Access Hospitals (CAHs) would pull the numerator and denominator from their EHR, or if they would pull that data from the HIE. If the numerator and denominator would come from the HIE, then hospitals and CAHs would not have sufficient data to report performance based measures.

### What are potential barriers for eligible hospitals and CAHs meeting the Query of PDMP measure as a performance-based measure?

• In addition to the above potential issue, the other primary barrier we are aware of is not having integration into the EHR workflow. Also, the degree of integration. If an EHR automatically queries for a provider and presents the information vs. requiring the provider to click a button in the interface to query. Also, whether a state allows a delegate (such as nurse or medical assistant) to query on the prescriber's behalf.

Would adoption and use of Health IT Modules certified to the "Prescription Drug Monitoring Program (PDMP) Databases—Query, receive, validate, parse, and filter" certification criterion proposed by ONC in the HTI–2 proposed rule (89 FR 63547), if this criterion were to be finalized, help to mitigate previously identified burden associated with implementing and reporting on a performance-based "Query of PDMP" measure?

• No, the certification criterion proposed by ONC in the HTI–2 proposed rule (89 FR 63547) would not alleviate any identified barriers that adopting PDMP query performance-based measures. The potential barriers identified with adopting performance-based measures do not relate to how the data is queried, received, validated, parsed, and filtered.

How would the adoption and use of Health IT Modules certified to the proposed "Prescription Drug Monitoring Program (PDMP) Databases—Query, receive, validate, parse, and filter" certification criterion, if it were finalized, impact the numerator and denominator of a potential performance-based PDMP measure?

• If both rules were passed it could impact the implementation of performance-based measures as both would likely require changes to technical systems which would further burden/strain both state, vendors, and hospital resources.

### What are other measure concepts we should consider that would allow us to focus on outcomes related to overdose prevention?

• There is data that shows patients with chronic pain who are on high dose opioids long term are at higher risk of overdose in the months after no longer receiving opioid prescriptions. CMS could consider measures that incentivize providers to follow up with patients in this situation to help protect against overdose.

Should we explore measures related to monitoring data from PDMPs that could assess multiple opioid prescriptions, opioid prescriptions from multiple prescribers, combined opioid and benzodiazepine prescriptions, or very high standardized dosage of opioids prescribed?

• If CMS considers these measures, it should be cautious. New measures related to these instances could negatively impact pain patients, cancer patients, and patients in rural areas, as these groups may frequently require more than one opioid prescription and/or multiple providers. Anecdotally DOH has heard that the more onerous the requirements are to meet, the more likely the provider may stop treating patients with *medications*.

### What measure concepts related to the use of PDMPs are likely to involve the lowest effort and provide the highest value to the health care community?

• Further incentivizing health care organizations to integrate with PDMPs would provide high value as we see queries of the PDMP rise significantly when facilities integrate EHRs with the PDMP. Cost and time/resources as the most common reasons given for delaying PDMP integration.

# What challenges exist, if any, around expanding the Query of PDMP measure to include all Schedule II drugs?

• Given that all PDMPs collect all Schedule II drugs WA DOH does not feel this expansion would impose any real challenges. By including the entire schedule instead of picking certain drugs from in it, it could make the analytics easier to pull.

## What are the potential benefits versus risks of expanding the Query of PDMP measure to include all Schedule II drugs?

• The key benefit is ensuring non-opioid Schedule II drugs are also reviewed as part of treatment decisions. DOH has seen other Schedule II drugs being misused such as stimulants. If providers have automated their query of the PDMP the risks (burden to providers) should not be an issue.

# Would expanding the Query of PDMP measure to Schedule II nonopioid drugs create barriers for patients appropriately prescribed Schedule II non-opioid drugs (for example, central nervous stimulants appropriately prescribed for ADHD)?

• Risk of barriers exists, and it is difficult to know how all providers will respond. Some may find it easier to stop prescribing these medications and refer to specialists (that are hard to get scheduled with) if they see potential issues rather than trying to help the patient with complex medical diagnosis.

# How should CMS account for varying levels of readiness and capacity for eligible hospitals and CAHs to meet an expanded scope of the measure, particularly for small and rural providers, including eligible hospitals and CAHs?

• CMS should account for smaller facilities through use of exclusions such as their CEHRT does not have PDMP query capabilities in place. To put the burden of an expanded scope on lesser

resources facilities would only make it harder for them to provide care and operate successfully financially.

#### **RFI Regarding Performance-Based Measures (Page 18374)**

What aspects of data quality and usability are most appropriate and valuable to measure in the context of the Public Health and Clinical Data Exchange objective of the Medicare Promoting Interoperability Program (for example, timeliness and completeness of reporting)?

- Public health must move quickly to stop the spread of disease. Timeliness, accuracy and completeness are all very critical. In order to make informed policy decisions, complete data that properly covers the entire population, has the necessary fields populated, and does not contain errors is key. In particular, demographic fields are very critical to our work (address, date of birth) along with National Provider Identifier (NPI) for identifying the provider, and we experience issues with labs results being submitted with no LOINC or SNOMED codes (this has delayed onboarding of many organizations by up to a year or more).
- In relation to the above three attributes of the data, the laboratory confirmation of the disease being done promptly and reported without delay is the desired action which also affects the timeliness and completeness of reporting. A composite measure that captures the three attributes above would be helpful to track the surveillance system performance.

How could data completeness be defined? For instance, how should we define "complete data"? Should we consider a threshold approach, under which eligible hospitals and CAHs would attest that they are successfully sending complete data for a minimum set of data elements to a PHA?

• DOH believes that the American Immunization Registry Association (AIRA) has a robust data quality program. They define "completeness" as: "The degree to which full information about a data set, record, or individual data element is captured in the CDC's Immunization Information System (IIS) (i.e., the proportion of stored data with complete information measured against the potential of "100%")." As a member of AIRA who uses their data quality tools we have found this to work very well. CMS can learn more about the AIRA data quality program at - <u>https://www.immregistries.org/data-at-rest</u>. Other data quality metrics from AIRA we support CMS considering are Validity and Timeliness.

# Are there other metrics available that we should consider in the Medicare Promoting Interoperability Program that more directly relate to actions and outcomes that public health reporting is intended to enable (for example, overdose prevention)?

• CMS may consider adding death reporting. CDC has funded PHAs to report death data via FHIR to the National Center for Health Statistics. Death records are a large part of monitoring the overdose crisis. By having providers also report death records via FHIR, this would make the surveillance activities much timelier. Given this would be a new measure, perhaps adding it as a bonus measure would be a good place to start. PHAs still need federal funding to support not just sending death records via FHIR, but to receive them via FHIR.

Of the current types of public health data exchange reflected in the Public Health and Clinical Data Exchange objective measures, what use cases should we prioritize for a focus on data quality that would provide the highest value to the health care community while resulting in the least burden?

• Given the amazing work that AIRA has done in this space already, immunizations would likely be the least burdensome as a lot of data quality has already been standardized in this space. The value for providers is that with immunization it is not just sending data to public health but providing back critical immunization history and forecast information to inform provider treatment decisions. Also prioritizing eCR given the national hub used for data quality and routing could be a good use case to start with. The value to providers is the desire to end manual reporting of case reports to Public Health. A data quality focus in this area would help move providers and PHAs closer to that reality.

Currently, eligible hospitals and CAHs can earn 25 points for reporting on all six required measures. Under a revised scoring approach, should we specify that eligible hospitals and CAHs could earn up to 5 points for each measure, for a total of 30 points for the objective, but must earn at least 1 point for each measure to earn a score for the Medicare Promoting Interoperability program, in addition to meeting the overall threshold for the program?

• Any moves that further incentivize critical public health reporting would be welcome and appreciated.

## Should we score all public health measures for which we finalize a numerator and denominator based on performance? Or should we only score a subset of measures based on performance?

• To help drive data quality and ensure public health transactions are providing good data both to PHAs and Providers, DOH recommends scoring all public health measures where a numerator and denominator are finalized.

## What are the most promising uses of FHIR approaches to the public health reporting requirements under the Medicare Promoting Interoperability Program?

- FHIR is most promising for eCR where a FHIR IG is available. Most of the other measures so far have not had a FHIR IG available. We would encourage the creation of such IGs, perhaps using the FHIR Accelerator for Public Health Helios.
- The Public Health Reporting Measures IG would be great with the creation and addition of the measures libraries specific to public health system performance.

## What approaches have the most potential to reduce the burden of reporting on eligible hospitals and CAHs and increase the quality and timeliness of data submitted to PHAs?

• Continued development of FHIR. This will require the creation of FHIR IGs for the PH measures currently listed and adding new measures (birth and death reporting for example). This will also require investment in Public Health Infrastructure as very few PHAs have FHIR capabilities at this time. FHIR has shown it can be a much more efficient and effective method in reducing reporting burden (easier to implement) and has the potential to increase data quality and timeliness (APIs and Bulk FHIR).

• Continued adoption of eCR. The automated exchange of case report information between healthcare facilities and public health agencies reduces the required reporting burden on providers. It also does not disrupt their clinical workflow. Data on notifiable conditions are integrated into DOH surveillance systems at a fraction of the time manual reporting does, allowing for a reduction in response time in a public health emergency as well as for timelier and more complete data to support outbreak management, case investigation, and the monitoring of disease trends.

Use of FHIR APIs could ultimately result in consolidation of disparate functions in EHRs that are currently being used to support different types of public health data exchange, for instance, through availability of an API that makes data available for a range of public health use cases. If these approaches are implemented in certified health IT in the future, should we consider streamlining or reduce the number of measures required in the Medicare Promoting Interoperability Program?

• The ability to have a single API support multiple PHA measures would likely reduce the burden of exchange on our clinical partners. DOH would support streamlining measures in a future state where this is possible if the rules still required all the important public health data transactions (ELR, eCR, IIS) within that API and that the overall points for Public Health Exchange does not decrease. DOH would not want to see the importance of public health exchange diminished by lowering the points gained via the public health measure(s).

Thank you for the opportunity to comment. DOH strongly supports continued incentives to promote data exchange with clinical partners for syndromic surveillance, chronic disease (e.g. cancer) vital records, case report, disease and clinical registries and others. Federal support for public health reporting must remain strong to support the health of all Americans. DOH believes interoperability rules must strengthen the vital role public health plays in health security and public safety. DOH looks forward to partnering with HHS to further this important work.

We encourage coordinated participation with our HHS partners and with public health agencies to continue to advance interoperability between public health and healthcare. If you have any questions, please contact DOH's Federal and Regulatory Affairs Director, Mike Ellsworth at <u>Michael.Ellsworth@doh.wa.gov</u> or Governor Ferguson's Director of Federal and Inter-State Affairs, Rose Minor at <u>Rose.Minor@gov.wa.gov</u>

Sincerely, Mai

Dr. Bryant Thomas Karras, MD, FACMI Chief Medical Informatics Officer Washington State Department of Health