Response to Comments

Quality Measures and Procedures for the Hospital Inpatient Quality Reporting Program for the FY 2023 IPPS Annual Payment Updates (OMB Control No. 0938-1022) FY 2021 IPPS/LTCH PPS Final Rule (RIN 0938-AU11, CMS-1735-F)

1) Comment: Many commenters did not support the proposal to require additional quarters of eCQM data in light of the impact of the COVID–19 public health emergency (PHE) on hospitals and requested that eCQM reporting and submission requirements for the CY 2021 reporting period/FY 2023 payment determination remain at one self-selected calendar quarter of data for each of the four self-selected eCQMs. Commenters noted that the COVID–19 PHE has shifted focus away from normal operations, increased burden, and strained hospital resources, particularly impacting staffing and technology. A few commenters indicated that the COVID–19 PHE has limited hospitals' ability to make the IT investments needed to report additional quarters of data. Commenters stated that internal resources have been reallocated or reassigned, that current IT investments are focused on caring for COVID–19 patients via telehealth, and that hospitals are already experiencing burdens or costs associated with implementing additional regulations on information blocking and interoperability. In addition, commenters stated that hospitals are complying with numerous federal and state data reporting requirements related to COVID–19 lab testing, patient volumes, and bed capacity, which are constantly evolving. The commenters stated that, while the duration of the COVID–19 PHE remains uncertain, hospitals expect to be operating in this challenging environment well into CY 2021. Given these challenges, commenters requested that reporting and submission requirements for the CY 2021 reporting period/FY 2023 payment determination remain at one selfselected calendar quarter of data so that hospitals may choose the fourth quarter, providing time for EHR upgrades. A few commenters expressed concern that the proposal could cause hospitals to lose their entire annual payment update (¼ for the IQR, and ¾ for the Promoting Interoperability Program) for failing to meet an eCQM mandate that their EHR vendors cannot deliver due to the pandemic and other competing federal EHR-related mandates. Another commenter stated that the COVID–19 PHE's impact on hospital volumes may render data less reliable. A commenter suggested that CMS continue to monitor the COVID–19 PHE and the extent to which hospitals have recovered to inform the exact timeframe to begin increasing eCQM reporting requirements. Response: We thank the commenters for their comments and recognize the burden that the COVID–19 PHE has had on the healthcare system. In response to the significant impact of the COVID–19 PHE on hospitals, we issued an array of temporary regulatory waivers and exceptions affecting a wide crosssection of Medicare participation, eligibility, and payment requirements, in an effort to reduce burden, provide flexibility to hospitals, and help hospitals maximize their capacity focus on patient care. These waivers and exceptions reduce hospital paperwork burden and reporting requirements, increase flexibility for surge capacity and patient quarantine, allow providers to expand access to telehealth, and enable hospitals to enhance their workforces, among other benefits. In relation to the Hospital IQR Program, we issued a nationwide extraordinary circumstances exception (ECE) that excepted certain data reporting requirements and extended numerous deadlines. Additionally, under the Hospital IQR Program ECE Policy, hospitals may request an exception if they are

unable to fulfill program requirements due to extraordinary circumstances not within their control. We refer readers to eCQM ECE resources on QualityNet and 42 CFR 412.140(c)(2) for more information. As noted previously, our current policy for eCQM reporting requires hospitals to report only one, selfselected calendar quarter of data for four self-selected eCQMs for the CY 2020 reporting period/FY 2022 payment determination. Calendar year 2021 will be the fifth year that hospitals have submitted eCQM data, and current reporting and submission requirements were established in the FY 2018 IPPS/ LTCH PPS final rule. In that final rule (82 FR 38361), we finalized a policy that eCQM reporting would be required for one self-selected quarter of data for 4 self-selected eCQMs, rather than finalizing our proposal to require reporting on the first three calendar quarters of data for 6 eCQMs in the FY 2018 proposed rule (82 FR 20050 through20051) or continuing our previously finalized policy to require hospitals to submit one full calendar year of data for 8 eCQMs (81 FR 57152). We made this change due to stakeholder concerns about the challenges associated with collecting and reporting eCQM data (82 FR 38355 through 38361). We believed it was important to give stakeholders more time to build and refine their EHR systems and gain experience reporting eCQMs (82 FR 38356). At that time, we stated our intention to gradually transition toward more robust eCQM reporting (82 FR 38356), and we reiterated that intention in a subsequent final rule (84 FR 42502). As stated in the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32836), we believe that increasing the number of quarters for which hospitals are required to report eCQM data will produce more comprehensive quality measure data for patients and providers and that submitting and evaluating multiple quarters of data would provide a more reliable and accurate picture of hospital performance. Internal review of Hospital IQR Program eCQM submissions data revealed that approximately 97 percent of eligible hospitals successfully submitted one quarter of eCQM data for four self-selected eCQMs for CY 2018 (84 FR 42458). We believe that hospitals have had adequate time to prepare for providing two quarters of data, especially given that hospitals may select to report the third and fourth quarters of CY 2021, allowing them to use the first half of CY 2021 to continue to prepare. After holding eCQM reporting and submission policies constant for a number of years in order to give hospitals and their vendors additional time to improve eCQM reporting capabilities, and stating our intention to transition to more robust reporting, we believe that it is time to increase the level of reporting in order to capture additional quarters of data. As we noted in the proposed rule, we believe that a single quarter of data is not enough to capture trends in performance over time. Our goal in proposing to progressively increase the number of quarters of data to be collected over 3 years was to strike an appropriate balance between increasing eCQM reporting and providing hospitals with the necessary time to implement such changes. If hospitals are concerned that their annual payment update may be impacted because vendors will be unable to meet the regulatory requirements related to the reporting of electronic clinical quality measures, we emphasize that hospitals may be eligible for an ECE under the IQR program as described above and further below.

2) **Comment:** A few commenters expressed concern about the amount of time that may be required for a hospital or their vendor to internally validate the data and/or create and review CCN files prior to data submission to CMS. A commenter stated the proposal amends more modest, previously finalized policies that hospitals relied on for planning and resource allocation purposes.

Response: We recognize that increasing the number of quarters of eCQM data to be reported can impact a hospital's resource use and refer readers to section XI.B.7 of the preamble of this final rule (information collection requirements) for a detailed discussion of our burden estimates associated with eCQM reporting and submission. We believe the long-term benefits associated with reporting a full year of electronic data will outweigh the burdens and that increasing the number of quarters for which hospitals are required to report eCQM data will produce more comprehensive and reliable quality information for patients and providers. We stated our intention in the FY 2018 IPPS/LTCH PPS final rule to gradually transition toward more robust eCQM reporting (82 FR 38356). We reiterated this stated goal to incrementally increase the use of EHR data for quality measurement in a subsequent final rule (84 FR 42502). We believe that taking an incremental approach to increasing eCQM reporting over a 3-year period will help to ease the burdens associated with reporting larger amounts of data and will provide hospitals and vendors with additional time to plan and sufficiently allocate resources for more robust eCQM reporting.

3) **Comment:** A few commenters requested that CMS require fewer quarters for validation. A commenter expressed concern that requiring four quarters of data for validation of both chart-abstracted measures and eCQMs would be too high a burden. This commenter recommended that CMS require no more than two quarters for validation.

   Response: While we agree with these commenters that restricting data validation to fewer calendar quarters may lead to some reduction to provider burden, we do not believe restricting data validation to fewer than two quarters would be consistent with our goals or approach, which has been designed to increase opportunities to detect poor reporting (77 FR 53540). Additionally, requiring fewer quarters of data for validation, which would reduce sample size, would impede the calculation of statistically significant validation scores needed to make payment determinations. We also note that the proposed increase in quarters for eCQM validation would occur in a gradual manner; hospitals would be validated on 2 quarters of CY 2021 eCQM data for validation affecting the FY 2024 payment determination, on 3 quarters of CY 2022 eCQM data for validation affecting the FY 2025 payment determination, and 4 quarters of CY 2023 eCQM data for validation affecting the FY 2026 payment determination and for subsequent years.

4) **Comment:** A commenter recommended against adopting a combined validation process because of the belief that a consolidated process would be more burdensome than individual processes due to the multiple measure types affected by the new process.

   Response: We are clarifying here that we are combining and aligning the hospital pool for the validation selection processes for the Hospital IQR Program and the HAC Reduction Program only. To be clear, these two programs will retain distinct and separate processes for validating submitted data, scoring, and applying any payment impacts to hospitals that fail validation. We refer readers to section VIII.A.10.f.2 below where we discuss the Hospital IQR Program validation process and section IV.M.6 where we discuss the HAC Reduction Program validation

process in more detail. While there may be some instances of increased burden for specific hospitals, we disagree with the commenter that this approach is more burdensome for the majority of hospitals. Under previously established validation requirements, hospitals selected for validation were already required to submit medical records for both clinical process of care and HAI measures. While our proposed policy would add the requirement for hospitals selected for validation to also submit medical records for eCQMs, the number of requested medical records for eCQM cases (eight cases per quarter over two quarters for a total of 16 cases for validation affecting the FY 2024 payment determination) remains low relative to clinical process of care cases (8 cases per quarter, over four quarters) and HAI cases (10 cases per quarter, over four quarters), that will be required for validation affecting the FY 2024 payment determination. Combining and aligning the hospital pool for validation between the programs would reduce burden by 400 hospitals per year starting with validation affecting the FY 2024 payment determination. This is supported by the majority of comments that we received in response to this proposal, which indicate that most hospitals believe that the combined process will be less burdensome. In addition, as discussed further below, we also proposed to reduce the overall number of hospitals selected for validation from 800 to up to 400, which reduces the overall validation burden.

5) **Comment:** A few commenters supported the proposal, but expressed concern that requiring electronic file submissions for chart-abstracted measure validation will be burdensome given the COVID–19 public health emergency (PHE) and asked CMS to delay this requirement. A commenter expressed concern that the influenza season and potential increased COVID– 19 case counts in fall 2020 would make it more difficult for facilities to implement such a change and asked that the proposal be delayed by one year. In the meantime, the commenter suggested reducing the reimbursement rate for the paper-based submissions to encourage electronic submissions and reduce the cost to CMS of administering the program.

   Response: We appreciate the commenters support for the proposal and recognize that some organizations do not submit validation data electronically and therefore will need to update their processes if they are selected for validation. However, we believe that the relative security of electronic submission versus mailing paper records outweighs the effort of updating processes. Furthermore, we believe that the reduced effort of printing, packaging, and mailing records will offset the burden of updating processes and reduce the impact of potential shipping delays on validation Based on our monitoring of medical record submissions to the CMS Clinical Data Abstraction Center (CDAC) contractor, we believe requiring electronic file submissions is a more effective and efficient process and will reduce burden for hospitals selected for validation, which we believe to be especially critical during the COVID–19 PHE and a potential increase in volume of influenza cases. We appreciate the commenter's suggestion to reduce reimbursement for paper charts to incentivize transition to electronic records, however, we believe that the efficiencies of electronic data submission outweigh any benefits to delaying this change.
6) **Comment:** A number of commenters expressed concern about an increase in burden related to our eCQM related proposals to increase the number of required reporting quarters for eCQM data and our proposal to begin publicly reporting eCQM data.

Response: We believe the long-term benefits associated with reporting a full year of electronic data will outweigh the burdens and that increasing the number of quarters for which hospitals are required to report eCQM data will produce more comprehensive and reliable quality information for patients and providers. We stated our intention in the FY 2018 IPPS/LTCH PPS final rule to gradually transition toward more robust eCQM reporting (82 FR 38356). We reiterated this stated goal to incrementally increase the use of HER data for quality measurement in a subsequent final rule (84 FR 42502). We believe that taking an incremental approach to increasing eCQM reporting over a 3-year period will help to ease the burdens associated with reporting larger amounts of data and will provide hospitals and vendors with additional time to plan and sufficiently allocate resources for more robust eCQM reporting. For a detailed discussion of comments we received on the information collection burden associated with the finalization of these proposals, please see section VIII.A.10 of the preamble of this final rule. We believe the finalization of these proposals effectively balances the burdens associated with increased reporting of eCQM data and the benefits of providing that quality data to patients and consumers.