

**Supporting Statement – Part A**  
**Quality Measures and Procedures for the Hospital Inpatient Quality Reporting Program**  
**for the FY 2022 IPPS Annual Payment Updates (OMB Control No. 0938-1022)**  
**FY 2020 IPPS/LTCH PPS Proposed Rule (RIN 0938-AT73, CMS-1716-P)**

**A. Background**

The Centers for Medicare & Medicaid Services (CMS) seeks to empower consumers to make more informed decisions about their health care and to promote higher quality of care through its quality reporting programs. The Hospital Inpatient Quality Reporting (IQR) Program was first established to implement Section 501(b) of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) (Pub. L. 108-173), which authorized CMS to pay hospitals that successfully reported quality measures a higher annual update to their payment rates. It builds on a voluntary Inpatient Quality Reporting Program, which remains in effect. Section 5001(a) of the Deficit Reduction Act of 2005 (DRA) (Pub. L. 109-171) revised the mechanism used to update the standardized amount for payment for hospital inpatient operating costs. This is reflected in sections 1886(b)(3)(B)(viii)(I) and (II) of the Social Security Act, which provide that the annual payment update (APU) will be reduced for any “subsection (d) hospital” that does not submit certain quality data in a form and manner, and at a time, specified by the Secretary.

Section 1886(o) of the Social Security Act mandates CMS’ transition from a passive supplier of health care to an active purchaser of quality care. Pursuant to section 1886(o)(2)(A) of the Social Security Act, CMS must select measures for the Hospital Value-Based Purchasing (VBP) Program from the measures (other than measures of readmissions) specified under the Hospital IQR Program. Consistent with this legislation, CMS established a Hospital VBP Program, beginning effective with payment adjustments on FY 2013 discharges, which qualifies hospitals for financial incentives based on their performance on a defined set of quality measures selected for the Hospital VBP Program from the measures specified under the Hospital IQR Program.

**1. Hospital IQR Program Quality Measures and Forms**

**a. Introduction**

The FY 2022 APU determination will be based on Hospital IQR Program data reported and supporting forms submitted by hospitals on chart-abstracted measures, patient surveys, and electronic clinical quality measures (eCQMs) for calendar year (CY) 2020 discharges. In an effort to reduce burden, a variety of different data collection mechanisms are employed, with every consideration taken to employ data and data collection systems already in place.

**b. Proposed New Measures and Related Reporting and Submission Requirements**

In the FY 2020 Inpatient Prospective Payment System (IPPS)/Long-Term Care Hospital (LTCH) PPS proposed rule, we are proposing to: (1) add two new electronic clinical quality measures (eCQMs) to the Hospital IQR Program eCQM measure set; (2) update eCQM reporting and submission requirements; (3) replace the claims-based version of a measure with a hybrid version; and (4) establish reporting and submission requirements for hybrid measures.

### ***Proposed New Electronic Clinical Quality Measures (eCQMs) and Related Reporting and Submission Requirements***

In the FY 2020 IPPS/LTCH PPS proposed rule, we are proposing to: (1) adopt two opioid-related eCQMs beginning with the CY 2021 reporting period/FY 2023 payment determination: (a) Safe Use of Opioids – Concurrent Prescribing eCQM (NQF #3316e), and (b) Hospital Harm – Opioid-Related Adverse Events eCQM; (2) continue eCQM reporting and submission requirements for the FYs 2022 through 2024 payment determinations; and (3) continue requiring that electronic health records (EHRs) be certified to all available eCQMs used in the Hospital IQR Program for the CY 2020 reporting period/FY 2022 payment determination and subsequent years. As further discussed in section B.12, below, we do not expect our eCQM-related proposals to change our information collection burden estimates.

### ***Proposed New Hybrid Hospital-Wide Readmission Measure and Related Reporting and Submission Requirements***

In the FY 2020 IPPS/LTCH PPS proposed rule, we are proposing to: (1) adopt the Hybrid Hospital-Wide Readmission Measure with Claims and Electronic Health Record Data (Hybrid HWR measure) (NQF #2879) in a stepwise manner; and (2) establish reporting and submission requirements for the Hybrid HWR measure. We expect these proposals will result in an overall increase in burden beginning with the FY 2024 payment determination. Details on these proposals, as well as the expected burden changes, are discussed further below in section B.12.

### ***Proposed Removal of Claims-Based Version of Hospital-Wide Readmission Measure***

Contingent on the adoption of the proposed Hybrid HWR measure, we are also proposing to remove the claims-only version of the Hospital-Wide All-Cause Unplanned Readmission Measure (Claims-based HWR measure) (NQF #1789) beginning with the FY 2026 payment determination. As further discussed in section B.12, below, we do not expect this proposal to affect our information collection burden estimates.

#### **c. Updated Hourly Wage Rate**

Based on the availability of more recent wage data, we have updated the wage rate used to calculate our burden estimates in the FY 2020 IPPS/LTCH PPS proposed rule and this PRA package as described in section B.12.a, below.

#### **d. Forms Used in the Data Collection Process**

In order to facilitate quality data reporting programs, several forms are necessary. These forms include:

- Hospital Inpatient Quality Reporting Notice of Participation
- Hospital Quality Reporting Data Accuracy and Completeness Acknowledgement (DACA)

- Hospital Compare Request Form for Withholding/Footnoting Data for Public Reporting
- Centers for Medicare & Medicaid Services (CMS) Inpatient Prospective Payment System (IPPS) Quality Reporting Programs Measure Exception Form for PC and HAI Data Submission
- CMS Quality Reporting Program APU Reconsideration Request Form
- CMS Hospital IQR Program Validation Review for Reconsideration Request Form
- CMS Quality Reporting Validation Educational Review Form
- Hospital Value-Based Purchasing (VBP) Program Review and Corrections Request Form
- Hospital Value-Based Purchasing (VBP) Program Appeal Request Form
- Hospital Value-Based Purchasing (VBP) Program Independent CMS Review Request Form
- Centers for Medicare & Medicaid Services (CMS) Quality Program Extraordinary Circumstances Exceptions (ECE) Request Form
- Validation templates for each of the following measures:
  - Central line-associated bloodstream infection (CLABSI);
  - Catheter-associated urinary tract infection (CAUTI);
  - Methicillin-resistant Staphylococcus Aureus (MRSA); and
  - Clostridium Difficile infection (CDI).

Only the Hospital Quality Reporting Data Accuracy and Completeness Acknowledgement (DACA) form must be completed each year by all hospitals participating in hospital quality reporting. This form only requires a hospital to check a box within the *QualityNet Secure Portal* affirming the accuracy and completeness of the data reported. The remainder of the forms are exceptions or one time only forms, and hospitals may not need to complete any of these forms in any given year.

The Hospital Inpatient Quality Reporting Notice of Participation is being resubmitted with streamlined content and conforming edits to the regulations at 42 CFR 412.140.

The DACA form is being resubmitted with streamlined content and improved readability.

The Hospital Compare Request Form for Withholding/Footnoting Data for Public Reporting is being resubmitted with minor clarifying edits and reorganizing of the Measures for Footnoting table to streamline content.

The CMS IPPS Quality Reporting Programs Measure Exception Form for PC and HAI Data Submission is being resubmitted to remove references to the emergency department (ED) measures, which will be removed from the Hospital IQR Program beginning with CY 2020 discharges per the FY 2019 IPPS/LTCH PPS final rule (83 FR 41567).

The CMS Quality Reporting Program APU Reconsideration Request Form is being resubmitted with the addition of Title to clarify who is filling out the form, and with the addition of sub-headings for eCQM Validation and Chart-Abstracted Validation.

The CMS Hospital IQR Program Validation Review for Reconsideration Request Form is being resubmitted to clarify instructions for submitting this form electronically since it is no longer required to be submitted by mail.

The CMS Quality Program Extraordinary Circumstances Exceptions Request Form is being resubmitted with conforming edits to the regulations at 42 CFR 412.140 and to list CrownWeb and non-measure related requirement(s) to the Data Requirement(s) Affected section.

The Validation templates for the CLABSI, CAUTI, MRSA, and CDI measures are being resubmitted to reflect the annual change in fiscal year and beginning reporting quarter, as well as new CDC pathogen lists.

All of the following other information collection forms will continue to be used in the Hospital IQR, and Hospital VBP, and Hospital-Acquired Condition (HAC) Reduction Programs without any modifications and are not being revised with this PRA package:

- CMS Quality Reporting Validation Educational Review Form
- Hospital Value-Based Purchasing (VBP) Program Review and Corrections Request Form
- Hospital Value-Based Purchasing (VBP) Program Appeal Request Form
- Hospital Value-Based Purchasing (VBP) Program Independent CMS Review Request Form

## **B. Justification**

### **1. Need and Legal Basis**

To begin participation in the Hospital IQR Program, all hospitals paid under the IPPS must complete a Hospital Inpatient Quality Reporting Notice of Participation. The Notice of Participation explains the participation and reporting requirements for the program. The form explains that in order to receive the full market basket update (or APU), the hospitals are agreeing to submit data on selected measures and allow CMS to publish their data for public viewing according to section 1886(b)(3)(B)(viii) of the Social Security Act. Other hospitals not paid under the IPPS, such as critical access hospitals, may also wish to voluntarily submit data and have their data published for public viewing. In order to accommodate these hospitals, a separate section of the participation form, referred to as the Optional Public Reporting Notice of Participation, is available for these hospitals to give CMS permission to collect and publish data that are voluntarily submitted by a hospital. These hospitals may choose to suppress a measure or measures prior to their posting on the CMS *Hospital Compare* website. In order to reduce burden, a hospital that indicated its intent to participate will be considered an active Hospital IQR Program participant until the hospital submits a withdrawal to CMS. Hospitals that no longer wish to participate in the Hospital IQR Program or those that no longer wish to submit data for publishing on *Hospital Compare* can notify CMS of their decision using the same form discussed above.

Annually, hospitals participating in hospital quality reporting use the Hospital Quality Reporting Data Accuracy and Completeness Acknowledgement (DACA) form after the end of each reporting year. This requirement was added based on a U.S. Government Accountability Office report from 2006 that recommended that CMS require hospitals to “formally attest to the completeness of the quality data that they submit.” This form is simply an acknowledgement that the data a hospital has submitted are complete and accurate and is completed annually.

Hospitals that voluntarily participate in quality reporting but are not paid under the IPPS may elect to have those data withheld from public reporting by completing the *Hospital Compare* Request Form for Withholding/Footnoting Data from Public Reporting. Once the form is submitted, data can be withheld for the quarter in which the form is submitted. However, the data will be released on *Hospital Compare* for subsequent releases unless the hospital submits a new Request Form for Withholding/Footnoting Data from Public Reporting indicating the measure(s) the hospital would like to withhold from public reporting for the period.

Hospitals that do not treat specified conditions or that do not have treatment locations defined for certain of the National Healthcare Safety Network’s healthcare-associated infection (HAI) measures (CLABSI, CAUTI, and Surgical Site Infection) have the option to either complete the enrollment process with National Healthcare Safety Network and indicate that they do not have patients who meet the measure requirements, or submit a CMS Inpatient Prospective Payment System (IPPS) Quality Reporting Programs Measure Exception Form for PC and HAI Data Submission. Hospitals that do not have an Obstetrics Department and do not deliver babies may also use this form for the PC-01: Elective Delivery measure. This Measure Exception Form will reduce the burden of completing the entire National Healthcare Safety Network enrollment process or entering zero denominator information for inapplicable measures for the hospitals that meet the exception requirements.

CMS selects up to 600 subsection (d) hospitals participating in the Hospital IQR Program on an annual basis for validation of chart-abstracted measures (77 FR 53551 through 53553). Each hospital selected for validation is to produce a list of patients/lab results associated with the particular HAI measure being validated. This process includes the use of validation templates for each of the CLABSI, CAUTI, MRSA, and CDI measures. In addition to validation of chart-abstracted measure data, up to 200 hospitals are also randomly selected for eCQM validation under the Hospital IQR Program (81 FR 57174 through 57178). We note that validation for the FY 2022 payment determination will be the last year for which the CLABSI, CAUTI, MRSA, and CDI measures will be validated under the Hospital IQR Program, and validation of those measures will transfer to the HAC Reduction Program beginning with FY 2023 (83 FR 41483).

When CMS determines that a hospital did not meet one or more of the Hospital IQR Program requirement(s), the hospital may submit a request for reconsideration to CMS using the CMS Quality Reporting Program APU Reconsideration Request Form, by the deadline identified on the Hospital IQR Program Annual Payment Update Notification Letter it received. For reconsideration requests related specifically to the validation requirements, hospitals may use the CMS Hospital IQR Program Validation Review for Reconsideration Request Form.

Hospitals may use the educational review process to correct disputed chart-abstracted measure validation results for the first three quarters of validation. To submit a formal request, hospitals can utilize the CMS Quality Reporting Validation Educational Review Form. We note that should the results of an educational review not be favorable to a hospital, a hospital may still also request reconsideration of those results using the CMS Hospital IQR Program Validation Review for Reconsideration Request Form.

CMS offers a process for hospitals to request exceptions to the reporting of required quality data, including eCQM data, for one or more quarters when a hospital experiences an extraordinary circumstance beyond the hospital's control. The CMS Quality Program Extraordinary Circumstances Exceptions Request Form indicates that for non-eCQM circumstances, the request must be submitted within 90 calendar days of an extraordinary circumstance event for all programs. In addition, the form indicates that for eCQM reporting circumstances under the Hospital IQR Program, the request must be submitted by April 1<sup>st</sup> following the end of a reporting period calendar year.

As noted above, we must select measures for the Hospital VBP Program from the measures (other than measures of readmissions) specified under the Hospital IQR Program. Hospitals may appeal the calculation of their performance assessment with respect to the performance standards, as well as their Total Performance Score (TPS), for the Hospital VBP Program. Hospitals may review and request recalculation of their hospital's performance scores on each condition, domain, and TPS using the Hospital Value-Based Purchasing (VBP) Program Review and Corrections Request Form within 30 calendar days of the posting date of the Value-Based Percentage Payment Summary Report. Hospitals may submit an appeal using the Hospital Value-Based Purchasing (VBP) Program Appeal Request Form within 30 calendar days of the date of receiving an adverse determination from CMS on their review and corrections request. Hospitals may submit a Hospital Value-Based Purchasing (VBP) Program Independent CMS Review Request Form within 30 days after they receive an adverse determination from CMS on their appeal.

## **2. Information Users**

The information from the Hospital IQR Program will be made available to hospitals for their use in internal quality improvement initiatives. CMS provides confidential feedback reports that hospitals may use to assess their performance and operationalize quality improvement activities throughout the quality reporting period. These reports include the data that CMS has collected from the hospital and the hospital's claims, and some also include information about how the hospital's data look relative to the performance of other hospitals. For example, the Facility, State and National (FSN) Report allows hospitals to compare their performance related to a specific measure during a specific timeframe, to the average performance of other hospitals at the state and national levels.

CMS will use the information collected from hospital quality reporting to set payment adjustments for value-based purchasing. For example, the Hospital VBP Program Baseline Measures Report allows hospitals to compare their performance for each measure to the program's benchmarks and achievement thresholds, which are obtained from the scores of all hospitals. These reports allow hospitals time to assess how their current performance in each measure could be scored in the upcoming Hospital VBP payment determinations while there is still time to target improvement activities related to specific measures so that their performance and scores can be maximized.

Hospital measure information is also used by CMS to direct its contractors to focus on particular areas of improvement and to develop quality improvement initiatives. Medicare beneficiaries experience a high rate of preventable readmissions, which are burdensome to patients and families, as well as costly. Quality Innovation Network-Quality Improvement Organizations (QIN-QIOs), under contract with CMS, use readmissions data from CMS to assist communities to reduce avoidable readmissions. For example, the QIN-QIO program helps communities with high readmission rates form local coalitions, identify the factors driving avoidable hospital readmissions in their area, and find ways to better coordinate care and to encourage patients to manage their health more actively.

Most importantly, this information is available to beneficiaries, as well as to the public, to provide hospital information to assist them in making decisions in choosing their health care providers. CMS sometimes conducts focus groups or market testing prior to publicly reporting hospital quality data on the *Hospital Compare* website in order to get feedback on ways to make the website more user-friendly. Feedback from these focus groups have helped CMS understand how beneficiaries and consumers use *Hospital Compare*. Under emergency circumstances, consumers choose hospitals based on proximity, reputation, prior experience, or their doctor's recommendation. For childbirth or elective hospital admissions, when patients and their family members may have the time and motivation to consider options and engage in informed decision making, they have expressed interest in information such as the provider's track record in treating their condition, safety and infection rates, and a hospital's recognized areas of expertise, as well as to take into consideration their doctor's recommendation.

## **3. Use of Information Technology**

To assist hospitals in standardizing data collection initiatives across the industry, CMS continues to improve data collection tools in order to make data submission easier for hospitals (e.g., the collection of electronic patient data in EHRs for eCQMs, the collection of data from paper medical records for chart-abstracted measures, or the collection of data from federal registries like the National Healthcare Safety Network), as well as to increase the utility of the data provided by the hospitals. In addition, we are advancing our ongoing commitment to promote efficiency through health information technology and increased EHR-based reporting, as demonstrated by the proposals we are making in the FY 2020 IPPS/LTCH PPS proposed rule, details of which are further discussed below.

For the claims-based measures, this section is not applicable, because claims-based measures can be calculated based on data that are already reported to the Medicare program for payment purposes. Therefore, no additional information technology will be required of hospitals for these measures.

#### **4. Duplication of Similar Information**

The information to be collected is not duplicative of similar information collected by CMS. We prioritize efforts to reduce reporting burden for the collection of quality of care information by utilizing electronic data that hospitals already report to The Joint Commission for accreditation, as well as aligning eCQMs and related reporting requirements with the Promoting Interoperability Program.

## 5. Small Business

Information collection requirements were designed to allow maximum flexibility specifically to small hospitals wishing to participate in hospital reporting. This effort will assist small hospitals in gathering information for their own quality improvement efforts. We define a “small hospital” as one with 1-99 inpatient beds. The Hospital IQR Program included 980 participating IPPS small hospitals in the FY 2019 program year.

## 6. Less Frequent Collection

We have designed the collection of quality measure data to be the minimum necessary for data validation and for calculation of summary figures to be used as reliable estimates of hospital performance. Frequency of data collection may vary (monthly, quarterly, annually, etc.) based on how a quality measure is specified. The following table details the frequency of data submission to CMS by measure type.

<i>Measure Type</i>	<i>Frequency of Data Submission</i>
Chart-abstracted clinical process of care	quarterly
EHR-based clinical process of care (i.e., eCQMs)	annual
EHR data for hybrid measures <sup>1</sup>	annual

## 7. Special Circumstances

Although participation in the Hospital IQR Program is voluntary on the part of subsection (d) hospitals, all eligible hospitals must submit these data and meet all other Hospital IQR Program requirements in order to receive their full APU for the given fiscal year. If a hospital does not submit the required data and meet all other Hospital IQR Program requirements, it would be subject to a reduced APU for a given fiscal year.

## 8. Federal Register Notice/Outside Consultation

A 60-day *Federal Register* notice of the FY 2020 IPPS/LTCH PPS proposed rule (RIN 0938-AT73, CMS-1716-P) published on May 3, 2019 (84 FR 19158). Comments will be submitted on this notice, and we will respond to those comments accordingly.

CMS is supported in this initiative by The Joint Commission, National Quality Forum (NQF), Measure Applications Partnership, Centers for Disease Control and Prevention, and Agency for Healthcare Research and Quality. These organizations collaborate with CMS on an ongoing basis, providing technical assistance in developing and/or identifying quality measures, and assisting in making the information accessible, understandable, and relevant to the public.

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<sup>1</sup> In the FY 2020 IPPS/LTCH PPS proposed rule, we are proposing to adopt the Hybrid Hospital-Wide Readmission Measure with Claims and Electronic Health Record Data (Hybrid HWR measure) (NQF #2879).

## **9. Payment/Gift to Respondent**

No payments or gifts will be given to respondents for participation. As noted in the FY 2017 IPPS/LTCH IPPS final rule (81 FR 57261), we reimburse hospitals directly for expenses associated with submission of charts for clinical process of care measure data validation – we reimburse hospitals at 12 cents per photocopied page; for hospitals providing charts digitally via a re-writable disc, such as encrypted CD-ROM, DVD, or flash drive or via secure file transfer, we reimburse hospitals at a rate of \$3.00 per record submitted and additionally at a rate of 40 cents per disc.

## **10. Confidentiality**

All information collected under this initiative will be maintained in strict accordance with statutes and regulations governing confidentiality requirements for Quality Improvement Organizations, which can be found at 42 CFR Part 480. In addition, the tools used for transmission of data are considered confidential forms of communication, and there are safeguards in place in accordance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy and Security Rules to protect the submission of patient information, at 45 CFR Part 160 and 164, Subparts A, C and E. The CMS clinical data warehouse also voluntarily meets or exceeds the HIPAA standards.

## **11. Sensitive Questions**

Case-specific clinical data elements will be collected and are necessary to calculate statistical measures. These statistical measures are the basis of all subsequent improvement initiatives derived from this collection and cannot be calculated without the case-specific data. These sensitive data will not, however, be released to the public. Only hospital-specific data will be released to the public after consent has been received from the hospital for the release. The patient-specific data remaining in the CMS clinical data warehouse after the data are aggregated for release for public reporting will continue to be subject to the strict confidentiality regulations in 42 CFR Part 480.

## **12. Burden Estimate (Total Hours & Wages)**

### **a. Background**

For the purposes of burden estimation, we assume all of the activities associated with the Hospital IQR Program for 3,300 IPPS hospitals and 1,100 non-IPPS hospitals will be completed by Medical Records and Health Information Technicians. These staff are qualified to complete the tasks associated with the chart-abstraction of patient data from medical records, the submission of electronic data from EHRs, and the submission of data to clinical registries, and the completion of any of the other applicable forms associated with activities related to the Hospital IQR Program.

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38501 through 38504) and FY 2019 IPPS/LTCH PPS final rule (83 FR 41689 through 41694), we estimated that the labor performed

could be accomplished by these staff based on a mean hourly wage in general medical and surgical hospitals of \$18.29 per hour. We note that since then, more recent wage data from the Bureau of Labor Statistics have become available, reflecting a median hourly wage of \$18.83 per hour for a Medical Records and Health Information Technician professional.<sup>2</sup> We calculated the cost of overhead, including fringe benefits, at 100% of the mean hourly wage, consistent with previous years. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly between employers, and because methods of estimating these costs vary widely in the literature. Nonetheless, we believe that doubling the hourly wage ( $\$18.83 \times 2 = \$37.66$ ) to estimate total cost is a reasonably accurate estimation method. As a result of the availability of this more recent wage data, we have updated the wage rate used in these calculations in the FY 2020 IPPS/LTCH PPS proposed rule and this corresponding PRA package to \$37.66.

Our burden estimates exclude burden associated with the National Healthcare Safety Network under OMB control number 0920-0666, the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey under OMB control number 0938-0981, and the Medicare Promoting Interoperability Program under OMB control number 0938-1158.

#### **b. Modified Estimates for the FY 2022 Payment Determination**

We previously submitted total annual burden estimates under this OMB control number for the FY 2022 payment determination as a result of policies finalized in the FY 2019 IPPS/LTCH PPS final rule. In the FY 2020 IPPS/LTCH PPS proposed rule, we are proposing: (1) eCQM reporting and submission requirements for the CY 2020 reporting period/FY 2022 payment determination; and (2) eCQM certification requirements for EHR technology beginning with the CY 2020 reporting period/FY 2022 payment determination. We do not expect these proposals to change our previously approved estimate of the total annual burden hours for the CY 2020 reporting period/FY 2022 payment determination, as further discussed below. However, due to the availability of more recent wage rate data as described above, we have revised our total annual cost estimates for the CY 2020 reporting period/FY 2022 payment determination and are requesting approval of these modified estimates, as further explained below.

##### *Proposed eCQM Reporting and Submission Requirements for FY 2022 Payment Determination*

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38355 through 38361) and FY 2019 IPPS/LTCH PPS final rule (83 FR 41602 through 41607), we finalized eCQM reporting and submission requirements such that hospitals submit one, self-selected calendar quarter of data for four self-selected eCQMs in the Hospital IQR Program measure set for the CYs 2017 through 2019 reporting periods/FYs 2019 through 2021 payment determinations. In the FY 2020 IPPS/LTCH PPS proposed rule, we are proposing to extend the same eCQM reporting and submission requirements for an additional two years, for the CYs 2020 and 2021 reporting periods/FYs 2022 and 2023 payment determinations.

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<sup>2</sup> U.S. Bureau of Labor Statistics. Occupational Outlook Handbook, Medical Records and Health Information Technicians. Available at: <https://www.bls.gov/ooh/healthcare/medical-records-and-health-information-technicians.htm>.

As these are the same eCQM reporting and submission requirements previously finalized, the same burden estimates of 40 minutes per hospital per year (10 minutes per record x 4 eCQMs x 1 quarter) would also apply to the CY 2020 reporting period/FY 2022 payment determination as proposed. Accordingly, we do not expect our proposed eCQM reporting and submission requirements to change our burden estimates for the CY 2020 reporting period/FY 2022 payment determination because we are proposing a continuation of existing policies.

#### *Proposed eCQM Certification Requirements Beginning With FY 2022 Payment Determination*

In the FY 2020 IPPS/LTCH PPS proposed rule, we are proposing to continue requiring that EHR technology used for eCQM reporting be certified to all available eCQMs used in the Hospital IQR Program for the CY 2020 reporting period/FY 2022 payment determination and subsequent years. We do not believe hospitals will experience an increase in information collection burden as a result of this proposal because this policy does not require hospitals to submit new data to CMS.

#### *Summary of Burden Hours*

Therefore, because we do not anticipate any change in burden hours as a result of the proposals discussed above, we believe our approved estimate of the total annual burden hours for the CY 2020 reporting period/FY 2022 payment determination under this OMB control number of 1,612,710 hours remains the same.

#### *Revised Total Cost Estimates for FY 2022 Payment Determination*

Due to the availability of more recent wage data, as discussed above, we have revised our total annual cost estimate for the CY 2020 reporting period/FY 2022 payment determination to reflect the updated wage rate. With the updated wage rate of \$37.66 per hour, we estimate a revised total cost of approximately \$60.7 million (1,612,710 hours x \$37.66 wage rate = \$60,734,658.60). This represents an increase in total costs of approximately \$1.7 million due to the updated wage rate, which was derived by subtracting the previously approved total cost estimate based on the old wage rate from the revised total cost estimate based on the updated wage rate (\$60,734,658.60 – \$58,992,931.80 = \$1,741,726.80). As a result of the updated wage rate, we are requesting approval of this revised total cost estimate for the CY 2020 reporting period/FY 2022 payment determination.

#### **c. Modified Estimates for the FY 2023 Payment Determination**

We previously submitted total annual burden estimates under this OMB control number for the FY 2023 payment determination as a result of policies finalized in the FY 2019 IPPS/LTCH PPS final rule. In the FY 2020 IPPS/LTCH PPS proposed rule, we are proposing: (1) to adopt two eCQMs beginning with the CY 2021 reporting period/FY 2023 payment determination; and (2) eCQM reporting and submission requirements for the CY 2021 reporting period/FY 2023 payment determination. We do not expect these proposals to change our approved estimates of the total annual burden hours for the CY 2021 reporting period/FY 2023 payment determination, as further discussed below. However, due to the availability of more recent wage rate data as

described above, we have revised our total annual cost estimates for the CY 2021 reporting period/FY 2023 payment determination and are requesting approval of these modified estimates, as further explained below.

#### *Proposed eCQM Reporting and Submission Requirements for FY 2023 Payment Determination*

As discussed above in section B.12.b (*Modified Estimates for the FY 2022 Payment Determination*), in the FY 2020 IPPS/LTCH PPS proposed rule, we are proposing to extend the same eCQM reporting and submission requirements previously finalized for the CYs 2017 and 2019 reporting periods/FYs 2019 through 2021 payment determinations for an additional two years, for the CYs 2020 and 2021 reporting periods/FYs 2022 and FY 2023 payment determinations.

We do not expect our proposed eCQM reporting and submission requirements to affect our burden estimates for the CY 2021 reporting period/FY 2023 payment determination because we are proposing a continuation of existing policies, as discussed above in section B.12.b (*Modified Estimates for the FY 2022 Payment Determination*).

#### *Proposed Adoption of Two Opioid-Related eCQMs Beginning With FY 2023 Payment Determination*

In the FY 2020 IPPS/LTCH PPS proposed rule, we are proposing to adopt two opioid-related eCQMs, the Safe Use of Opioids – Concurrent Prescribing eCQM (NQF #3316e) and the Hospital Harm – Opioid-Related Adverse Events eCQM, beginning with the CY 2021 reporting period/FY 2023 payment determination.

We do not believe that adding two new eCQMs to the eCQM measure set will affect the information collection burden of submitting information to CMS under the Hospital IQR Program. If the eCQM reporting and submission requirements we are proposing are finalized, hospitals would continue to submit one self-selected calendar quarter of data for four eCQMs each year. The two proposed eCQMs would be added to the eight available eCQMs in the eCQM measure set from which hospitals may choose to report in order to satisfy these requirements. In other words, if these two proposed eCQMs are added to the eCQM measure set, hospitals would still be required to report a total of four eCQMs as currently, and proposed to be, required. Therefore, we do not expect adopting these measures would impact our previous burden estimates for the CY 2021 reporting period/FY 2023 payment determination.

## *Summary of Burden Hours*

Therefore, because we do not anticipate any change in burden hours as a result of the proposals discussed above, we believe our approved estimate of the total annual burden hours for the CY 2021 reporting period/FY 2023 payment determination under this OMB control number of 1,569,510 hours remains the same.<sup>3</sup>

## *Revised Total Cost Estimates for FY 2023 Payment Determination*

Due to the availability of more recent wage data, as discussed above, we have revised our total annual cost estimate for the CY 2021 reporting period/FY 2023 payment determination to reflect the updated wage rate. With the updated wage rate of \$37.66 per hour, we estimate a revised total cost of approximately \$59.1 million (1,569,510 hours x \$37.66 wage rate = \$59,107,746.60). This represents an increase in total costs of approximately \$1.7 million due to the updated wage rate, which was derived by subtracting the previously approved total cost estimate based on the old wage rate from the revised total cost estimate based on the updated wage rate (\$59,107,746.60 – \$57,412,675.80 = \$1,695,070.80). As a result of the updated wage rate, we are requesting approval of this revised total cost estimate for the CY 2021 reporting period/FY 2023 payment determination.

### **d. Estimates for the FY 2024 Payment Determination**

In the FY 2020 IPPS/LTCH PPS proposed rule, we are proposing: (1) to adopt eCQM reporting and submission requirements for the CY 2022 reporting period/FY 2024 payment determination, which we do not expect will result in any changes to burden; and (2) to adopt the Hybrid Hospital-Wide Readmission Measure with Claims and Electronic Health Record Data (Hybrid HWR measure) (NQF #2879) into the Hospital IQR Program in a stepwise manner, beginning with two voluntary reporting periods followed by required reporting for subsequent years, which we expect would result in an overall increase in burden for participating hospitals. Details on these proposals, as well as the expected burden change as a result of our proposal to adopt the Hybrid HWR measure, are discussed further below.

## *Proposed eCQM Reporting and Submission Requirements for FY 2024 Payment Determination*

As previously discussed in section B.12.b (*Modified Estimates for the FY 2022 Payment Determination*) and section B.12.c (*Modified Estimates for the FY 2023 Payment Determination*), we are proposing to extend the same eCQM reporting and submission requirements previously finalized for the CYs 2017 through 2019 reporting periods/FYs 2019 through 2021 payment determinations such that hospitals submit one, self-selected calendar quarter of data for four self-selected eCQMs in the Hospital IQR Program measure set for the CYs 2020 and 2021 reporting periods/FYs 2022 and 2023 payment determinations.

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<sup>3</sup> We note that the total annual burden hours previously approved for the FY 2023 payment determination (1,569,510 hours) are less than those previously approved for the preceding FY 2022 payment determination (1,612,710 hours) due to policies finalized in the FY 2019 IPPS/LTCH PPS final rule.

In the FY 2020 IPPS/LTCH PPS proposed rule, we are proposing to change the eCQM reporting and submission requirements for the CY 2022 reporting period/FY 2024 payment determination, such that hospitals would report one self-selected calendar quarter of data for: (a) three self-selected eCQMs, and (b) the proposed Safe Use of Opioids – Concurrent Prescribing eCQM (NQF #3316e), for a total of four eCQMs. We note that the number of calendar quarters of data and total number of four eCQMs required would remain the same.

Because hospitals would still be required to submit one, self-selected calendar quarter of data for a total of four eCQMs in the Hospital IQR Program’s eCQM measure set under the eCQM reporting and submission requirements proposed for the CY 2022 reporting period/FY 2024 payment determination, we believe there will be no change in burden. The same burden estimates of 40 minutes per hospital per year (10 minutes per record x 4 eCQMs x 1 quarter) previously approved for the CYs 2017 through 2019 reporting periods/FYs 2019 through 2021 payment determinations would also apply to the CY 2022 reporting period/FY 2024 payment determination as proposed.

#### *Proposal to Adopt Hybrid HWR Measure – First Voluntary Reporting Period*

In the FY 2020 IPPS/LTCH PPS proposed rule, we are proposing to adopt the Hybrid HWR measure in a stepwise manner, beginning with two voluntary reporting periods that would run from July 1, 2021 through June 30, 2022, and from July 1, 2022 through June 30, 2023, before requiring reporting of the measure for the reporting period that would run from July 1, 2023 through June 30, 2024. We expect these proposals will affect our information collection burden estimates beginning with the first voluntary reporting period, which corresponds with the FY 2024 payment determination.

As a hybrid measure, this measure uses both claims-based data and EHR data, specifically, a set of core clinical data elements consisting of vital signs and laboratory test information and patient linking variables collected from hospitals’ EHR systems. We do not expect any additional burden on hospitals to report the claims-based portion of this measure because these data are already reported to the Medicare program for payment purposes.

We do, however, expect that hospitals will experience an increase in burden associated with reporting EHR data for the Hybrid HWR measure. Under our proposed reporting and submission requirements, hospitals would use the same submission process to submit EHR data for the Hybrid HWR measure as required for reporting eCQMs; specifically, these data would be reported using QRDA I files submitted to the CMS data receiving system, and using EHR technology certified to the 2015 Edition of Certified EHR Technology (CEHRT).

Accordingly, we expect the burden associated with reporting of EHR data for the Hybrid HWR measure to be similar to our estimates for reporting eCQMs; that is, 10 minutes per measure per quarter. Using the estimate of 10 minutes per measure per quarter (10 minutes x 1 measure x 4 quarters = 40 minutes) results in an increase in burden of 0.67 hours (40 minutes) per hospital on an annual basis.

Therefore, beginning with the first voluntary reporting period, which we propose would run from July 1, 2021 through June 30, 2022, and corresponds with the FY 2024 payment determination, we estimate a total annual burden increase of 2,211 hours (0.67 hours per hospital × 3,300 IPPS hospitals) for IPPS hospitals. Using the updated wage estimate described above, we estimate a total increase in costs of approximately \$83,266 (2,211 annual hours x \$37.66 hourly wage).

For non-IPPS hospitals, we estimate a total annual burden increase of 737 hours (0.67 hours per hospital x 1,100 non-IPPS hospitals). Using the updated wage estimate described above, we estimate a total increase in costs of approximately \$27,755 (737 annual hours x \$37.66 hourly wage).

In sum, we estimate a total burden increase of 2,948 hours (2,211 hours + 737 hours) and a total cost increase of approximately \$111,021 (\$83,266 + \$27,755) across all IPPS and non-IPPS hospitals associated with the first voluntary reporting period for the Hybrid HWR measure.

We note that while reporting during the first two years of this proposal would be voluntary, if our proposal to adopt the Hybrid HWR measure is finalized, we would encourage all hospitals to submit data for the Hybrid HWR measure during the voluntary reporting periods. For that reason, our burden estimates are based on the expectation that all hospitals will participate across the two voluntary reporting periods, the reporting period in which required reporting of the measure begins, and subsequent reporting periods.

**Table 1. Burden Calculations for the Hospital IQR Program Measure Set and Other Activities for the FY 2024 Payment Determination**

Information Collection Activity	Estimated time per record (minutes)	Number reporting quarters per year	Number of hospitals reporting	Average number records per hospital per quarter	Annual burden (hours) per Hospital	Total Annual Burden (Hours) Across Hospitals
<b>CHART-ABSTRACTED MEASURES</b>						
<b>IPPS Hospitals (3,300)</b>						
Sepsis Measure	60	4	3,300	100	400	1,320,000
Perinatal Care (PC)	10	4	3,300	76	51	167,200
<b>Chart-Based Subtotal (IPPS)</b>						<b>1,487,200</b>
<b>Non-IPPS Hospitals (1,100)</b>						
Sepsis Measure	60	4	362	25	100	36,200
Perinatal Care (PC)	10	4	334	21	14	4,676
<b>Chart-Based Subtotal (Non-IPPS)</b>						<b>40,876</b>
<b>Chart-Based Subtotal (IPPS and Non-IPPS)</b>						<b>1,528,076</b>
<b>eQMs</b>						
<b>IPPS Hospitals (3,300)</b>						
Reporting 4 eQMs	40	1	3,300	1	0.67	2,200

<b>Non-IPPS Hospitals (1,100)</b>						
Reporting 4 eCQMs	40	1	1,100	1	0.67	734
<b>eCQM Subtotal (IPPS and Non-IPPS)</b>						<b>2,934</b>
<b>HYBRID MEASURES</b>						
<b>IPPS Hospitals (3,300)</b>						
Reporting Hybrid HWR Measure	10	4	3,300	1	0.67	2,211
<b>Non-IPPS Hospitals (1,100)</b>						
Reporting Hybrid HWR Measure	10	4	1,100	1	0.67	737
<b>Hybrid Subtotal (IPPS and Non-IPPS)</b>						<b>2,948</b>
<b>OTHER ACTIVITIES</b>						
<b>All Hospitals (3,300 IPPS + 1,100 Non-IPPS)</b>						
Population and sampling for ongoing measure sets	15	4	4,400	4	4	17,600
Review reports for claims-based measure sets	60	4	4,400	1	4	17,600
eCQM Validation (IPPS hospitals only)	80	1	200	8	11	2,200
All other forms used in the data collection process	15	1	4,400	1	0.25	1,100
<b>Other Activities Subtotal</b>						<b>38,500</b>
<b>TOTAL</b>						<b>1,572,458</b>

### Summary

Given the estimated burden increase associated with our proposal to adopt the Hybrid HWR measure, we estimate a total annual burden of 1,572,458 hours (1,569,510 hours + 2,211 annual hours for IPPS hospitals + 737 annual hours for non-IPPS hospitals) beginning with the FY 2024 payment determination. Using the updated wage estimate described above, we estimate a total cost of approximately \$59.2 million (1,572,458 hours x \$37.66 hourly wage). We are requesting approval of these burden estimates for the FY 2024 payment determination.

### e. Estimates for the FY 2025 Payment Determination

As further discussed below, we do not anticipate any changes to our burden estimate for the FY 2025 payment determination, compared to our burden estimate for the FY 2024 payment determination, as a result of our proposal to adopt the Hybrid HWR measure.

#### *Proposal to Adopt Hybrid HWR Measure – Second Voluntary Reporting Period*

As discussed above, under our proposal to adopt the Hybrid HWR measure in a stepwise manner, the second voluntary reporting period would run from July 1, 2022 through June 30, 2023, which corresponds with the FY 2025 payment determination.

We believe there will be no change in burden for the FY 2025 payment determination, compared to our burden estimate for the FY 2024 payment determination, because our burden estimate for the first voluntary reporting period, as discussed in preceding section B.12.d above (*Estimates for the FY 2024 Payment Determination*), reflects the ongoing burden associated with reporting the Hybrid HWR measure beginning with the FY 2024 payment determination. Also, as previously noted, our burden estimates are based on the expectation that all hospitals will participate across the two voluntary reporting periods, the reporting period in which required reporting of the measure begins, and subsequent reporting periods.

For the FY 2025 payment determination, we are requesting approval of the same burden estimates detailed above for the FY 2024 payment determination; that is, a total annual burden of 1,572,458 hours (1,569,510 hours + 2,211 annual hours for IPPS hospitals + 737 annual hours for non-IPPS hospitals) and a total cost estimate of approximately \$59.2 million (1,572,458 hours x \$37.66 hourly wage).

#### **f. Estimates for the FY 2026 Payment Determination**

As further discussed below, we do not anticipate any changes to our burden estimates for the FY 2026 payment determination, compared to our burden estimates for the FYs 2024 and 2025 payment determinations, as a result of our proposal to adopt the Hybrid HWR measure. We also do not anticipate any changes to our burden estimates as a result of our proposal to remove the claims-based version of the HWR measure beginning with the FY 2026 payment determination.

##### *Proposal to Adopt Hybrid HWR Measure – First Required Reporting Period*

As discussed above, under our proposal to adopt the Hybrid HWR measure in a stepwise manner, following two voluntary reporting periods, we are proposing to require reporting of the Hybrid HWR measure for the reporting period that would run from July 1, 2023 through June 30, 2024 for the FY 2026 payment determination, and for subsequent years.

For the same reasons discussed above in section B.12.e (*Estimates for the FY 2025 Payment Determination*), we believe there will be no change in burden for the FY 2026 payment determination compared to our burden estimates for the FYs 2024 and 2025 payment determinations. In particular, our burden estimates for the two voluntary reporting periods reflect an expectation that all hospitals will participate across the two voluntary reporting periods, so when the Hybrid HWR measure becomes a required measure beginning with the FY 2026 payment determination, we expect the same number of hospitals would continue to report on this measure.

##### *Proposal to Remove Claims-Based Version of HWR Measure*

In conjunction with our proposal to adopt the Hybrid HWR measure, we are proposing to remove the claims-based version of the HWR measure, beginning with the FY 2026 payment determination when required reporting of the Hybrid HWR measure begins.

Because the claims-based version of the HWR measure is calculated using data that are already reported to the Medicare program for payment purposes, we do not anticipate that removing this measure will result in any changes in burden.

Therefore, for the FY 2026 payment determination, we are requesting approval of the same burden estimates detailed above for the FYs 2024 and 2025 payment determinations; that is, a total annual burden of 1,572,458 hours (1,569,510 hours + 2,211 annual hours for IPPS hospitals + 737 annual hours for non-IPPS hospitals) and a total cost estimate of approximately \$59.2 million (1,572,458 hours x \$37.66 hourly wage).

### **g. Additional Information on Burden Estimates**

Time estimates for activities other than abstracting charts, including completion of the forms listed in section A.1.d above other than the HAI Validation Templates, routine reporting of population and sampling numbers for ongoing chart-abstracted measures, and review of reports were made in consultation with our Hospital IQR Program support contractor, which is responsible for routine interface with hospitals and Quality Improvement Organizations regarding Hospital IQR Program requirements. We define “*all other forms used in the data collection process*” as the forms listed in section A.1.d above except the HAI Validation Templates, which are separately included in the burden estimate for validation.<sup>4</sup> Consistent with estimates in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49762), we estimate a burden of 15 minutes per hospital to complete all applicable forms.

Other than the DACA form, the forms listed in section A.1.d would not be filled out by hospitals on a regular basis. Because the CMS Quality Reporting Program Extraordinary Circumstances Exceptions (ECE) Request Form would be used across ten quality programs (Hospital IQR Program, Hospital Outpatient Reporting Program, Inpatient Psychiatric Facility Quality Reporting Program, PPS-Exempt Cancer Hospital Quality Reporting Program, Ambulatory Surgical Center Quality Reporting Program, Hospital VBP Program, Hospital-Acquired Condition Reduction Program, Hospital Readmissions Reduction Program, End Stage Renal Disease Quality Incentive Program, and Skilled Nursing Facility Value-Based Purchasing Program), we have included a burden calculation using this form as an example of “all other forms” within this PRA package. This form is intended to be submitted by participants only in the event of an extraordinary circumstance or disaster if they seek an exception from data reporting requirements due to such extraordinary circumstance. For example, in CY 2017, 166 ECE requests were submitted by hospitals for an exception from reporting requirements in the Hospital IQR Program. Based on our estimation of 15 minutes/record to submit the ECE Request Form, the total burden calculation for the submission of 166 ECE requests was 2,490 minutes (or 41.5 hours) across 3,300 IPPS hospitals. Note that non-IPPS hospitals have no need for this form because they participate in quality data reporting on a voluntary basis. We were conservative in our estimate (provided in Table 1 above) of 1,100 hours across all IPPS and non-IPPS hospitals, thus this 41.5 hours ECE Request Form burden estimation is accounted for in that figure.

### **13. Capital Costs (Maintenance of Capital Costs)**

There are no capital costs.

### **14. Cost to Federal Government**

The cost to the Federal Government includes costs associated with the collection and validation of the data. These costs are estimated at \$10,050,000 annually for the validation and quality

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<sup>4</sup> As noted above, validation for the FY 2022 payment determination will be the last year for which the CLABSI, CAUTI, MRSA, and CDI measures will be validated under the Hospital IQR Program, and validation of those measures will transfer to the HAC Reduction Program beginning with FY 2023 (83 FR 41483).

reporting contracts. Additionally, this program takes three CMS staff at a GS-13 level to operate. GS-13 approximate annual salary is \$99,172 for an additional cost of \$297,516.

For the claims-based measures, the cost to the Federal Government is minimal. CMS uses data from the CMS National Claims History system that are already being collected for provider reimbursement; therefore, no additional data will need to be submitted by hospitals for claims-based measures.

## **15. Program or Burden Changes**

We previously requested and received approval for total annual burden estimates under this OMB control number for the CY 2019 reporting period/FY 2021 payment determination of 2,520,100 hours as a result of policies finalized in the FY 2019 IPPS/LTCH PPS final rule. Additionally, we previously submitted total annual burden estimates under this OMB control number for the CY 2020 reporting period/FY 2022 payment determination of 1,612,710 hours – a total burden decrease of 907,390 hours – as a result of policies finalized in the FY 2019 IPPS/LTCH PPS final rule.

As discussed above in section B.12.b, we do not anticipate any change in burden for the CY 2020 reporting period/FY 2022 payment determination as a result of the proposals contained in the FY 2020 IPPS/LTCH PPS proposed rule. However, we have revised our total annual cost estimate due to the availability of more recent wage data.

As a result of the proposals contained in the FY 2020 IPPS/LTCH PPS proposed rule, we anticipate a slight overall increase in total burden hours associated with the proposal to adopt the Hybrid HWR measure into the Hospital IQR Program beginning with the FY 2024 payment determination. Specifically, we anticipate an increase of 2,948 in total annual burden hours, or \$111,022 in total annual costs, associated with our proposal to adopt the Hybrid HWR measure in a stepwise fashion across both IPPS and non-IPPS hospitals, beginning with the FY 2024 payment determination.

We have updated the hourly wage rate based on the availability of more recent wage data, which has resulted in a slight increase to our annual cost estimates previously approved for the FYs 2022 and 2023 payment determinations, but without change to the estimated total burden hours.

## **16. Publication/Tabulation Data**

The goal of the data collection is to tabulate and publish hospital-specific data. We will continue to display hospital quality information for public viewing as required by Social Security Act sections 1886(b)(3)(B)(viii)(VII) for the Hospital IQR Program, 1886(o)(10) for the Hospital VBP Program, 1886(p)(6) for the HAC Reduction Program, and 1886(q)(6) for the Hospital Readmissions Reduction Program. Hospital data from these initiatives are currently used to populate the *Hospital Compare* website, [www.hospitalcompare.hhs.gov](http://www.hospitalcompare.hhs.gov). Data are presented on *Hospital Compare* in a format mainly aimed towards consumers, patients, and the general public, providing access to hospital-specific quality measure performance rates along with state and national performance rates. For certain outcome and cost measures, data are presented on *Hospital Compare* in performance categories of Better, No Different, or Worse than the National Rate. More detailed measure data, including the data used for *Hospital Compare*, are also available to the public as downloadable files at <https://data.medicare.gov>. Hospital quality data on *Hospital Compare* are updated on a quarterly basis.

## **17. Expiration Date**

We will display the approved expiration date on each of the forms listed above in section A.1.d, which would become available on our *QualityNet* website ([www.qualitynet.org](http://www.qualitynet.org)). We will also display the approved expiration date prominently on our *QualityNet* website's Hospital IQR Program pages used to document our measure specifications and reporting guidance.

## **18. Certification Statement**

We are not claiming any exceptions to the Certification for Paperwork Reduction Act Submissions Statement.