The Centers for Medicare & Medicaid Services (CMS) has now displayed the Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment System for Calendar Year (CY) 2018. The CY 2018 Final Rule, CMS-1678-FC (PDF), was placed on display November 1, 2017, and will be published in the Federal Register on November 13, 2017. Changes to the Hospital Outpatient Quality Reporting (OQR) Program begin on page 837 of the PDF. Changes affecting the ASC Quality Reporting (ASCQR) Program begin on page 922 of the PDF. As an additional resource, CMS has provided a fact sheet addressing the changes proposed in the Final Rule for 2018.

An overview of the updates to the programs is available from the Hospital Outpatient Regulations and Notices and the ASC Regulations and Notices sections of the CMS.gov website. These changes are applicable to services furnished on or after January 1, 2018.
Disclaimer:

This information was prepared as a service to the public, and is not intended to grant rights or impose obligations. This presentation may contain references or links to statutes, regulations, or other policy materials. The information provided is only intended to be a general summary. It is not intended to take the place of either the written law or regulations. We encourage readers to review the specific statutes, regulations, and other interpretive materials for a full and accurate statement of their contents.
DEPARTMENT OF HEALTH AND
HUMAN SERVICES
Centers for Medicare & Medicaid
Services
42 CFR Parts 414, 416, and 419
[CMS–1678–FC]
RIN 0938–AT03
Medicare Program: Hospital Outpatient
Prospective Payment and Ambulatory
Surgical Center Payment Systems and
Quality Reporting Programs
AGENCY: Centers for Medicare &
Medicaid Services (CMS), HHS.
ACTION: Final rule with comment period.

SUMMARY: This final rule with comment period revises the Medicare hospital outpatient prospective payment system (OPPS) and the Medicare ambulatory surgical center (ASC) payment system for CY 2018 to implement changes arising from our continuing experience with these systems. In this final rule with comment period, we describe the changes to the amounts and factors used to determine the payment rates for Medicare services paid under the OPPS and those paid under the ASC payment system. In addition, this final rule with comment period updates and refines the requirements for the Hospital Outpatient Quality Reporting (OQR) Program and the ASC Quality Reporting (ASCQR) Program.

DATES:
Effective date: This final rule with comment period is effective on January 1, 2018, unless otherwise noted. Comment period: To be assured consideration, comments on the payment classifications assigned to HCPCS codes identified in Addenda B, AA, and BB with the comment indicator “NI” and on other areas specified throughout this final rule with comment period must be received at one of the addresses provided in the ADDRESSES section no later than 5 p.m. EST on December 31, 2017.
Addenda Available Only Through the Internet on the CMS Web Site

In the past, a majority of the Addenda referred to in our OPPS/ASC proposed and final rules were published in the Federal Register as part of the annual rulemakings. However, beginning with the CY 2012 OPPS/ASC proposed rule, all of the Addenda no longer appear in the Federal Register as part of the annual OPPS/ASC proposed and final rules to decrease administrative burden and reduce costs associated with publishing lengthy tables. Instead, these Addenda are published and available only on the CMS Web site. The Addenda relating to the OPPS are available at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html. The Addenda relating to the ASC payment system are available at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.

Patients over Paperwork Initiative

CMS recently launched the Patients over Paperwork Initiative, a cross-cutting, collaborative process that evaluates and streamlines regulations with a goal to reduce unnecessary burden, increase efficiencies, and improve the beneficiary experience. Through the Patients over Paperwork Initiative, CMS, along with its partners and stakeholders, is committed to removing regulatory obstacles that get in the way of providers spending time with patients. Among the efforts to reduce regulatory burden in the Hospital Outpatient Prospective Payment System final rule include:

- CMS is reinstating the non-enforcement of direct supervision requirements for outpatient therapeutic services for Critical Access Hospitals and small rural hospitals having 100 or fewer beds for CYs 2018 and 2019.
- CMS is finalizing the removal of three Ambulatory Surgical Center Quality Reporting (ASCQR) Program quality measures for the CY 2019 payment determination and subsequent years. Removal of these measures would alleviate maintenance costs and administrative burdens to the ASCs, resulting in a burden reduction of 1,314 hours and saving $48,066 in CY 2019.
- CMS is also finalizing the removal of 6 Hospital Outpatient Quality Reporting (OQR) Program quality measures, resulting in a burden reduction of 457,490 hours and saving $16.7 million in CY 2020 for hospitals.
OPPS Final Payment Policy Changes for 2018

OPPS Payment Update
CMS is increasing the OPPS payment rates by 1.35 percent for 2018. The change is based on the hospital market basket increase of 2.7 percent minus both a 0.6 percentage point adjustment for multi-factor productivity and a 0.75 percentage point adjustment required by law. After considering all other policy changes under the final rule, including estimated spending for pass-through payments, CMS estimates an overall impact of 1.4 percent payment increase for providers paid under the OPPS in CY 2018.

Payment for Drugs and Biologicals (“Drugs”) Purchased through the 340B Drug Pricing Program
To address recent trends of increasing drug prices, for which some of the cost burden falls to Medicare beneficiaries, CMS is finalizing a change to the payment rate for certain Medicare Part B drugs purchased by hospitals through the 340B Program in order to lower the cost of drugs for Medicare beneficiaries.

Supervision of Hospital Outpatient Therapeutic Services
In the CY 2009 and CY 2010 OPPS/ASC proposed rule and final rule with comment period, CMS clarified that direct physician supervision is generally required for hospital outpatient therapeutic services that are furnished in hospitals, critical access hospitals (CAHs), and in provider-based departments of hospitals. For several years, there has been a moratorium on the enforcement of the direct supervision requirement for CAHs and small rural hospitals, with the latest moratorium on enforcement expiring on December 31, 2016. In this final rule, CMS is reinstating the non-enforcement of direct supervision requirements for outpatient therapeutic services for CAHs and small rural hospitals having 100 or fewer beds for CYs 2018 and 2019.

Packaging of Low-Cost Drug Administration Services
A tenet of a prospective payment system is to package payment of all integral, ancillary, supportive, dependent, or adjunctive services into payment for primary services. In CY 2014, CMS proposed but did not finalize a policy to package all add-on procedures, including drug administration add-on services. In CY 2015, CMS conditionally packaged payment for ancillary services assigned to an ambulatory payment classification group with a geometric mean cost of $100 or less, but excluded certain low-cost drug administration services from this policy. To continue CMS’ work toward bundling payments under the OPPS and encouraging hospital efficiencies, CMS is finalizing its proposal to conditionally package payment for low-cost drug administration services.
Inpatient Only List
The Medicare inpatient-only (IPO) list includes procedures that are typically only provided in the inpatient setting and therefore are not paid under the OPPS. Each year, CMS uses established criteria to review the IPO list and determine whether or not any procedures should be removed from the list. For CY 2018, CMS is removing total knee arthroplasty from the IPO list as well as five other procedures. CMS is also adding one procedure to the IPO list in response to public comments. In addition, CMS is precluding the Recovery Audit Contractors from conducting “site of service” reviews of outpatient total knee arthroplasty procedures for a period of two years.

High Cost/Low Cost Threshold for Packaged Skin Substitutes
Under the OPPS, payment for skin substitutes – products used to aid in wound healing – is packaged into the payment for their associated surgical procedures. These products are assigned to either a “high cost group” or a “low cost group” depending on how costly they are relative to certain cost thresholds. Consistent with current policy, CMS proposed to assign skin substitutes with a geometric mean unit cost (MUC) or a per day cost (PDC) that exceeds either the MUC threshold or the PDC threshold to the high cost group. In addition for CY 2018, CMS is finalizing its proposal that a skin substitute product that does not exceed either the CY 2018 MUC or PDC threshold for CY 2018, but was assigned to the high cost group for CY 2017, will be assigned to the high cost group for CY 2018. The goal of this policy is to maintain similar levels of payment for skin substitute products for CY 2018 while CMS analyzes the current skin substitute payment methodology to determine whether refinements to the existing methodologies may be warranted.

Revisions to the Laboratory Date of Service Policy
For a clinical diagnostic laboratory test, the date of service (DOS) is typically the date the specimen was collected, unless certain conditions are met. CMS considered potential modifications to the DOS policy that would allow laboratories to bill Medicare directly for molecular pathology tests and certain ADLTs which are excluded from the OPPS packaging policy and ordered less than 14 days following the date of the patient’s discharge from the hospital.

After considering the public comments received, we added an additional exception to the current laboratory DOS regulations, effective January 1, 2018. This new exception to the laboratory DOS policy generally permits laboratories to bill Medicare directly for ADLTs and molecular pathology tests excluded from OPPS packaging policy if the specimen was collected from a hospital outpatient during a hospital outpatient encounter and the test was performed following the patient’s discharge from the hospital outpatient department.
Partial Hospitalization Program (PHP) Rate Setting
The CY 2018 OPPS/ASC final rule with comment period updates Medicare payment rates for PHP services furnished in hospital outpatient departments and Community Mental Health Centers (CMHCs). The PHPs are structured intensive outpatient programs consisting of a group of mental health services paid on a per diem basis under the OPPS, based on PHP per diem costs.

For 2018, we are maintaining the methodology established in CY 2017. In CY 2017, CMS implemented a unified rate structure with a single PHP payment rate for each provider type for days with 3 or more services per day.

Social Risk Factors
As we consider the feasibility of collecting patient-level data and the impact of strategies to account for social risk factors through further analysis, we will also continue to evaluate the reporting burden on providers and patients. We thank all of the commenters for their input and will consider all suggestions as we continue to assess the issue of accounting for social risk factors within individual measures, the Hospital OQR Program as a whole, and across CMS quality programs.
Removal of Quality Measures from the Hospital OQR Program Measure Set

Hospital Outpatient Quality Reporting (OQR) Program

The Hospital OQR Program is a quality reporting program for outpatient hospital services. The Hospital OQR Program requires hospital outpatient facilities to submit data on quality measures and meet certain program requirements to avoid a reduction of 2.0 percentage points to their annual payment update.

In the CY 2018 OPPS/ASC final rule, CMS is finalizing proposals that balance the value of quality data with efforts to limit provider burden. CMS is finalizing the removal of 6 measures for this setting, resulting in a burden reduction of 457,490 hours and $16.7 million with respect to requirements for the CY 2020 payment determination. The measures being removed are:

- **OP-21: Median Time to Pain Management for Long Bone Fracture**, which measures the median time from emergency department (ED) arrival to time of initial oral, nasal, or parenteral pain medication (opioid and non-opioid) administration for emergency department patients with a principal diagnosis of long bone fracture. *This measure is being finalized for removal beginning with the CY 2020 payment determination.*

- **OP-26: Hospital Outpatient Volume Data on Selected Outpatient Surgical Procedures**, which assesses the aggregate count of selected, higher volume, surgical procedures performed in Hospital Outpatient Departments. *This measure is being finalized for removal beginning with the CY 2020 payment determination.*

- **OP-1: Median Time to Fibrinolysis**, which assesses the median time from ED arrival to administration of fibrinolytic therapy in ED patients with ST-segment elevation on the ECG performed closest to ED arrival and prior to transfer. *This measure was proposed to be removed beginning with the CY 2021 payment determination, but is being finalized for removal beginning with the CY 2020 payment determination in response to public comments requesting earlier removal.*

- **OP-4: Aspirin at Arrival**, which assesses the rate of patients with chest pain or possible heart attack who received aspirin within 24 hours of arrival or before transferring from the emergency department. *This measure was proposed to be removed beginning with the CY 2021 payment determination, but is being finalized for removal beginning with*
the CY 2020 payment determination in response to public comments requesting earlier removal.

- **OP-20: Door to Diagnostic Evaluation by a Qualified Medical Professional**, which assesses the time from ED arrival to provider contact for emergency department patients. *This measure was proposed to be removed beginning with the CY 2021 payment determination, but is being finalized for removal beginning with the CY 2020 payment determination in response to public comments requesting earlier removal.*

- **OP-25: Safe Surgery Checklist Use**, which assesses whether a hospital employed a safe surgery checklist that covered each of the three critical perioperative periods (prior to administering anesthesia, prior to skin incision, and prior to patient leaving the operating room) for the entire data collection period. *This measure was proposed to be removed beginning with the CY 2021 payment determination, but is being finalized for removal beginning with the CY 2020 payment determination in response to public comments requesting earlier removal.*

- **OP–37a–e**: Additionally, CMS is finalizing the proposal to delay the mandatory implementation of the *Consumer Assessment of Healthcare Providers and Systems Outpatient and Ambulatory Surgery Survey (OAS CAHPS)* under the Hospital OQR Program beginning with the CY 2018 data collection until further action in future rulemaking.
Newly Finalized Hospital OQR Program Measure Set For the CY 2020 Payment Determination And Subsequent Years

Measure name
OP–2: Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival.
OP–3: Median Time to Transfer to Another Facility for Acute Coronary Intervention.
OP–5: Median Time to ECG. †
OP–8: MRI Lumbar Spine for Low Back Pain.
OP–9: Mammography Follow-up Rates.
OP–12: The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into their ONC-Certified EHR System as Discrete Searchable Data.
OP–13: Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low-Risk Surgery.
OP–14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus Computed Tomography (CT).
OP–17: Tracking Clinical Results between Visits. †
OP–18: Median Time from ED Arrival to ED Departure for Discharged ED Patients.
OP–22: Left Without Being Seen. †
OP–23: Head CT or MRI Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT or MRI Scan Interpretation Within 45 minutes of ED Arrival.
OP–29: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients.*
OP–30: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use.*
OP–31: Cataracts: Improvement in Patient’s Visual Function within 90 Days Following Cataract Surgery. **
OP–32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy.
OP–33: External Beam Radiotherapy for Bone Metastases.
OP–35: Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy.
OP–36: Hospital Visits after Hospital Outpatient Surgery.
OP–37a: OAS CAHPS—About Facilities and Staff. ***
OP–37b: OAS CAHPS—Communication About Procedure. ***
OP–37c: OAS CAHPS—Preparation for Discharge and Recovery. ***
OP–37d: OAS CAHPS—Overall Rating of Facility. ***
OP–37e: OAS CAHPS—Recommendation of Facility. ***

† We note that NQF endorsement for this measure was removed.
O  OP–26: Procedure categories and corresponding HCPCS codes are located at: https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=196289981244.
* We note that measure name was revised to reflect NQF title.
** Measure voluntarily collected as set forth in section XIII.D.3.b. of the CY 2015 OPPS/ASC final rule with comment period (79 FR 66946 through 66947).
*** Measure reporting delayed beginning with CY 2018 reporting and for subsequent years as discussed in section XIII.B.5. of this final rule with comment period.
**Hospital OQR Program Measures and Topics for Future Consideration**

In the CY 2018 OPPS/ASC proposed rule (82 FR 33678), we requested public comment on: (1) Future measure topics; and (2) future development of OP–2: Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival as an electronic clinical quality measure (eCQM). These are discussed in detail below.

**Future Measure Topics**

We are moving towards the use of outcome measures and away from the use of clinical process measures across our Medicare quality reporting and value-based purchasing programs. We invited public comments on possible measure topics for future consideration in the Hospital OQR Program. We specifically requested comment on any outcome measures that would be useful to add to the Hospital OQR Program as well as any clinical process measures that should be eliminated from the Hospital OQR Program.

**Comment:** A few commenters recommended that we adopt the eCQM version of OP–18: Median Time from ED Arrival to ED Departure for Discharged ED Patients.

**Response:** We thank the commenters for their feedback. We will consider these suggestions as we consider including and developing eCQMs for future rulemaking.

**Comment:** Several commenters suggested measure topics for future consideration, including measures that address Total Knee Arthroplasty (TKA) and Total Hip Arthroplasty (THA) procedures and measures that address recommended vaccines for adults, including pneumococcal immunization measures. A few commenters noted support for outcome measures, and recommended that CMS engage with stakeholders in identifying priority measurement areas. One commenter specifically recommended patient reported outcomes and patient reported experience measures. A commenter recommended the inclusion of pain experience and management measures. One commenter recommended the following topic areas for quality measures: Patient safety outcomes, readmission rates, risk-adjusted mortality, effective patient transitions, diabetes, obesity, and guidelines for overused procedures, end of life care according to preferences, cost per episode, behavioral health and patient experience.

**Response:** We thank the commenters for their recommendations and suggestions and agree that there are additional high priority topic measurement areas that may be appropriate for the Hospital OQR Program. We will consider the suggested topic areas for future rulemaking and intend to work with stakeholders as we continue to develop the Hospital OQR Program measure set.
Possible Future Adoption of the Electronic Version of OP–2: Fibrinolytic Therapy Received Within 30 Minutes of Emergency Department Arrival

We have previously stated that automated electronic extraction and reporting of clinical quality data, including measure results calculated automatically by appropriately certified health IT, could significantly reduce the administrative burden on hospitals under the Hospital OQR Program (81 FR 79785). In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79786), some commenters supported CMS' goal to incorporate electronic clinical quality measures (eCQMs) in the Hospital OQR Program. OP–2: Fibrinolytic Therapy Received Within 30 Minutes of Emergency Department Arrival was finalized in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66865), where it was designated as ED–AMI–3. In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68761), the measure was re-labeled as OP–2 for the CY 2010 payment determination and subsequent years. OP–2 measures the number of AMI patients receiving fibrinolytic therapy during the ED visit with a time from hospital arrival to fibrinolysis of 30 minutes or less. We are considering developing OP–2: Fibrinolytic Therapy Received Within 30 Minutes of Emergency Department Arrival as an eCQM and proposing the eCQM in future rulemaking. We note that since OP–2 is not yet developed as an eCQM; electronic measure specifications are not available at this time. We are considering OP–2: Fibrinolytic Therapy Received Within 30 Minutes of Emergency Department Arrival in particular because we believe this measure is the most feasible out of all the existing Hospital OQR Program measures for development as an eCQM. We invited public comment on the possible future development and future adoption of an eCQM version of OP–2: Fibrinolytic Therapy Received Within 30 Minutes of Emergency Department Arrival.

Comment: A few commenters supported the adoption of an eCQM version of OP–2: Fibrinolytic Therapy Received Within 30 Minutes of Emergency Department Arrival. Several commenters noted their support for the adoption of eCQMs, but expressed concern about the future adoption of an eCQM version OP–2: Fibrinolytic Therapy Received Within 30 Minutes of Emergency Department Arrival in the Hospital OQR Program noting that other measures, such as OP–18, are already specified as an eCQM and that other measures may be more relevant to the Hospital OQR Program since fibrinolytic therapy is not always appropriate with the increasing availability of cardiac catheterization labs.

Response: We will consider OP–18 for future rulemaking. In addition, while we acknowledge that OP–2 may not be relevant to all hospitals due to the increased availability of cardiac catheterization labs, we believe this measure would be important for smaller hospitals that continue to rely on fibrinolytic therapy. We thank the commenters for their feedback and will consider these concerns and suggestions before we decide whether to develop an eCQM version of OP–2: Fibrinolytic Therapy Received Within 30 Minutes of Emergency Department Arrival or propose the eCQM in future rulemaking.
Comment: Other commenters opposed the adoption of eCQMs in the Hospital OQR Program and expressed concern that eCQMs add, rather than reduce, administrative burden. Some commenters recommended that CMS delay implementation of eCQMs in the Hospital OQR Program until the vendor and CMS systems issues noted in Hospital IQR Program rulemaking are addressed and until the Hospital IQR Program demonstrates accurate and feasible submission of electronic data.

Response: In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38355), commenters raised concerns about EHR system upgrades, the difficulty of transitioning to a new EHR vendor, and updating to new editions of certified health IT. We appreciate commenters sharing their concerns about the challenges associated with eCQM reporting, including the significant expenditure of resources required to make necessary changes to health IT systems, documentation or utilization of EHRs, and workflow process changes and acknowledge commenters’ feedback that many hospitals may not be ready to report eCQMs. We will take lessons learned from eCQM submission in the Hospital IQR Program into consideration as we develop policy for the Hospital OQR Program.

As we stated in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57177) regarding the Hospital IQR Program, however, we acknowledge that there are initial costs, but believe that long-term benefits associated with electronic data capture outweigh those costs. In addition, as we stated in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49696) regarding the Hospital IQR Program, we believe that it is appropriate to consider reporting of eCQMs given that measures available now and those being developed for the future are increasingly based on electronic standards.

We thank the commenters for their feedback and acknowledge the concerns raised. We will consider these concerns and suggestions as we further consider developing OP–2: Fibrinolytic Therapy Received Within 30 Minutes of Emergency Department Arrival as an eCQM or proposing the eCQM in future rulemaking.
Public Display of Quality Measures

Public Reporting of OP–18c: Median Time From Emergency Department Arrival to Emergency Department Departure for Discharged Emergency Department Patients—Psychiatric/Mental Health Patients

OP–18 Median Time from ED Arrival to ED Departure for Discharged ED Patients was finalized for reporting for the CY 2013 payment determination and subsequent years in the CY 2011 OPPS/ASC final rule with comment period (75FR 72086). This measure addresses ED efficiency in the form of the median time from ED arrival to time of departure from the ED for patients discharged from the ED (also known as ED throughput). Reducing the time patients spend in the ED can improve the quality of care. As discussed in the measure specifications and Measure Information Form (MIF), OP–18 measure data is stratified into four separate calculations:

- OP–18a is defined as the overall rate
- OP–18b is defined as the reporting measure
- OP–18c is defined as assessing Psychiatric/Mental Health Patients
- OP–18d is defined as assessing Transfer Patients

Section 1833(t) (17) (E) of the Act, requires that the Secretary establish procedures to make data collected under the Hospital OQR Program available to the public and that such procedures must ensure that a hospital has the opportunity to review the data that are to be made public, with respect to the hospital prior to such data being made public. Currently, and as detailed in the OP–18 MIF, the OP–18 measure publicly reports data only for the calculations designated as OP–18b: Median Time from Emergency Department Arrival to Emergency Department Departure for Discharged Emergency Department Patients—Reporting Measure, which excludes psychiatric/mental health patients and transfer patients.

The ICD–10 diagnostic codes for OP–18c include numerous substance abuse codes for inclusion in this subset, along with numerous nonsubstance abuse codes. We believe it is important to publicly report data for OP–18c (Median Time from emergency Department Arrival to Emergency Department Departure for Discharged Emergency Department Patients—psychiatric/Mental Health Patients) to address a behavioral health gap in the publicly reported Hospital OQR Program measure set. Therefore, in the CY 2018 OPPS/ASC proposed rule (82 FR 33679), we proposed to also publicly report OP–18c and begin public reporting as early as July of 2018 using data from patient encounters during the third quarter of 2017.
In addition, we would make corresponding updates to our MIF to reflect these proposals, such as:

- Renaming OP–18b from “Median Time from Emergency Department Arrival to Emergency Department Departure for Discharged Emergency Department Patients—Reporting Measure” to “OP–18b: Median Time from Emergency Department Arrival to Emergency Department Departure for Discharged Emergency Department Patients—Excluding Psychiatric/Mental Health Patients and transfer Patients;”
- Modifying the form to reflect that OP–18c would also be publicly reported

Administrative changes made to the MIF would not affect hospital reporting requirements or burden. The data required for public reporting are already collected and submitted by participating outpatient hospital departments and our proposal to publicly report OP–18c does not create additional burden.

We note these data in accordance with our previously established 30-day preview period procedures (81 FR 79791). In developing this proposal, we also considered proposing to publicly report around July 2019 (not 2018 as proposed) using data from patient encounters occurring during the first quarter of 2018. However, we decided against this timeline, because under this reporting option, we would not be able to publicly report behavioral health data until as early as July of 2019, creating a delay in our efforts to address the behavioral health data gap in the publicly reported measure set.

We invited public comment on our proposal to publicly report OP–18c: Median Time from Emergency Department Arrival to Emergency Department Departure for Discharged Emergency Department Patients—Psychiatric/Mental Health Patients beginning with third quarter 2017 data as discussed above.

The comments received have shed some light on aspects of this particular subset of data that may need additional consideration prior to posting on the consumer-facing Hospital Compare Web site. We acknowledge commenters’ concerns regarding unintended consequences, including that the time to discharge for mental health patients may be influenced, in part, by the availability of community resources and that the measure could be perceived as creating pressure on providers to inappropriately limit care in order to quickly discharge mental health
patients. Literature has shown that the number of inpatient psychiatric beds as decreased from 400,000 in 1970 to 50,000 in 2006.

Therefore, after considering the public comments we received, including these additional factors, we would like to err on the side of caution and take additional time for further consideration prior to posting this particular subset of data on Hospital Compare, a consumer facing Web site. As background, we typically allow 30 days for hospitals to preview their data two months prior to public reporting, after which we deliver final public reporting files for the Hospital Compare Web site (77 FR 68483).

Simultaneously, in addition to posting on Hospital Compare, Hospital OQR Program quality measure data are also typically published on data.medicare.gov in downloadable data files. While we will not publicly report OP–18c on Hospital Compare, we will instead publish it on data.medicare.gov. Affected parties will be notified via CMS listservs, CMS email blasts, national provider calls, and QualityNet announcements regarding the release of preview reports followed by the posting of data on a Web site other than Hospital Compare (76 FR74453).

Based on the public comments we received, we intend to make measure data available in a downloadable data file rather than on Hospital Compare so that we may continue to evaluate the concerns raised by commenters regarding unintended consequences. We believe this modified approach to our original proposal is more appropriate than publishing on Hospital Compare, which is more public facing, because we want to avoid any potential circumstance in which the publication of these data exacerbate the concerns raised by commenters. We continue to believe the measure provides value to hospital quality improvement efforts and to patients. However, out of an abundance of caution, we intend to make data available on data.medicare.gov instead of Hospital Compare until we have been able to evaluate the concerns raised by commenters.

To be clear, data for what is referred to as OP–18b Median Time from Emergency Department Arrival to Emergency Department Departure for Discharged Emergency Department Patients—Reporting Measure will still continue to be made available on Hospital Compare as it has in the past.
In addition, in accordance with our decision to not publish OP–18c data on Hospital Compare, we are also not finalizing the proposed measure subset name changes or MIF form changes described in our proposal. We will continue to work toward finding the best means to make this subset of information more easily understandable to the public and consider other measures to help fill the behavioral health gap in the future.

After consideration of the public comments we received, we are finalizing the proposal, with modification, as discussed in our response above, such that we will make OP–18c rates available to the public on https://data.medicare.gov in downloadable files. We will take additional time to further assess how best to make this subset of data available on the Hospital Compare Web site for consumers.

In addition, we are not finalizing our proposals to:

- Rename OP–18b from “Median Time from Emergency Department Arrival to Emergency Department Departure for Discharged Emergency Department Patients—Reporting Measure” to “OP 18b: Median Time from Emergency Department Arrival to Emergency Department Departure for Discharged Emergency Department Patients—Excluding Psychiatric/Mental Health Patients and Transfer Patients;”
- Modify the MIF to reflect that OP–18c would also be publicly reported on Hospital Compare.
Form, Manner, and Timing of Data Submitted for the Hospital OQR Program

Hospital OQR Program Annual Payment Determinations

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75110 through 75111) and the CY 2016 OPPS/ASC final rule with comment period (80 FR 70519 through 70520), we specified our data submission deadlines. We also codified our submission requirements at 42 CFR 19.46(c). We refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70519 through 70520), where we finalized our proposal to shift the quarters upon which the Hospital OQR Program payment determinations are based, beginning with the CY 2018 payment determination. The finalized deadlines for the CY 2020 payment determination and subsequent years are illustrated in the tables below.

<table>
<thead>
<tr>
<th>CY 2020 Payment Determination and Subsequent Years</th>
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<tbody>
<tr>
<td><strong>Patient Encounter Quarter</strong></td>
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<tr>
<td>Q2 2018 (April 1–June 30)</td>
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<tr>
<td>Q3 2018 (July 1–September)</td>
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<td>Q4 2018 (October 1–December 31)</td>
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<td>Q1 2019 (January 1–March 31)</td>
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For the CY 2020 payment determination and subsequent years, we proposed to revise the data submission requirements for hospitals that did not participate in the previous year’s Hospital OQR Program. Specifically, we proposed to revise the first quarter for which newly participating hospitals are required to submit data (see details below). We did not propose any changes to the previously finalized data submission deadlines for each quarter. In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68482), we finalized the following data submission requirements for hospitals that did not participate in the previous year’s Hospital OQR Program:

- If a hospital has a Medicare acceptance date before January 1 of the year prior to the affected annual payment update, the hospital must submit data beginning with encounters occurring during the first calendar quarter of the year prior to the affected annual payment update.
- If a hospital has a Medicare acceptance date on or after January 1 of the year prior to the affected annual payment update, the hospital must submit data for encounters...
beginning with the first full quarter following submission of the completed Hospital OQR Program Notice of Participation Form

- Hospitals with a Medicare acceptance date before or after January 1 of the year prior to an affected annual payment update must follow data submission deadlines as posted on the QualityNet Web site.

These policies are also codified at 42 CFR 419.46(c) (3).

In the CY 2018 OPPS/ASC proposed rule (82 FR 33680), we proposed to:

1. Align the timeline specifying the initial quarter for which hospitals must submit data for all hospitals that did not participate in the previous year’s Hospital OQR Program, rather than specifying different timelines for hospitals with Medicare acceptance dates before versus after January 1 of the year prior to an affected annual payment update

2. Make conforming revisions at 42 CFR 419.46(c)

Specifically, we proposed that any hospital that did not participate in the previous year’s Hospital OQR Program must submit data beginning with encounters occurring during the first calendar quarter of the year prior to the affected annual payment update. We note that hospitals must still follow data submission deadlines corresponding to the quarter for which they are reporting data as posted on the QualityNet Web site.

We invited public comment on our proposals to align the initial data submission timeline for all hospitals that did not participate in the previous year’s Hospital OQR Program and to make conforming revisions at 42 CFR 419.46(c)

We did not receive any public comment on our proposals. Therefore, we are finalizing our proposals to align the initial data submission timeline for all hospitals that did not participate in the previous year’s Hospital OQR Program and to make conforming revisions at 42 CFR 419.46(c) (3), as proposed.
Requirements for Chart-Abstracted Measures Where Patient-Level Data Are Submitted Directly to CMS for the CY 2020 Payment Determination and Subsequent Years

The following previously finalized Hospital OQR Program chart abstracted measures will require patient-level data to be submitted for the CY 2020 payment determination and subsequent years:

- OP–2: Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival
- OP–3: Median Time to Transfer to Another Facility for Acute Coronary Intervention
- OP–5: Median Time to ECG
- OP–18: Median Time from ED Arrival to ED Departure for Discharged ED Patients
- OP–23: Head CT Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke Patients who Received Head CT Scan Interpretation Within 45 Minutes of ED Arrival
Claims-Based Measure Data Requirements for the CY 2020 Payment Determination and Subsequent Years

There are a total of nine claims-based measures for the CY 2020 payment determination and subsequent years:

- OP–8: MRI Lumbar Spine for Low Back Pain
- OP–9: Mammography Follow-Up Rates
- OP–10: Abdomen CT—Use of Contrast Material
- OP–11: Thorax CT—Use of Contrast Material
- OP–13: Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low Risk Surgery
- OP–14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus Computed Tomography (CT)
- OP–32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy
- OP–35: Admissions and Emergency Department Visits for Patients Receiving Outpatient Chemotherapy
- OP–36: Hospital Visits after Hospital Outpatient Surgery
Web-Based Measures

The following web-based quality measures previously finalized and retained in the Hospital OQR Program will require data to be submitted via a Web-based tool (CMS’ QualityNet Web site or CDC’s NHSN Web site) for the CY 2020 payment determination and subsequent years:

- OP–12: The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into their ONC Certified EHR System as Discrete Searchable Data (via CMS’ QualityNet Web site)
- OP–17: Tracking Clinical Results between Visits (via CMS’ QualityNet Web site)
- OP–27: Influenza Vaccination Coverage among Healthcare Personnel (via the CDC NHSN Web site)
- OP–29: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients (via CMS’ QualityNet Web site)
- OP–30: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use (via CMS’ QualityNet Web site)
- OP–31: Cataracts: Improvement in Patient’s Visual Function within 90 Days Following Cataract Surgery (via CMS’ QualityNet Web site)
- OP–33: External Beam Radiotherapy (EBRT) for Bone Metastases (via CMS’ QualityNet Web site)
Newly Finalized Hospital OQR Program Measure Set for the CY 2020 Payment Determination and Subsequent Years

In the CY 2018 OPPS/ASC proposed rule (82 FR 33676), we did not propose any new measures for the Hospital OQR Program.
Hospital OQR Program Validation Requirements for Chart-Abstracted Measure Data Submitted Directly to CMS for the CY 2020 Payment Determination and Subsequent Years

In the CY 2018 OPPS/ASC proposed rule (82 FR 33682), we:

- Clarified the hospital selection process previously finalized for validation
- Proposed to codify the procedures for targeting hospitals at 42 CFR 419.46(e)
- Proposed to formalize and update our educational review process

These are discussed in more detail below:

Clarification

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74485), we finalized a validation selection process in which we select a random sample of 450 hospitals for validation purposes, and select an additional 50 hospitals based on the following specific criteria:

- Hospital fails the validation requirement that applies to the previous year’s payment determination; or
- Hospital has an outlier value for a measure based on the data it submits. We defined an “outlier value” for purposes of this targeting as a measure value that appears to deviate markedly from the measure values for other hospitals. Specifically, we would select hospitals for validation if their measure value for a measure is greater than 5 standard deviations from the mean, placing the expected occurrence of such a value outside of this range at 1 in 1,744,278.

We note that the criteria for targeting 50 outlier hospitals, described above, does not specify whether high or low performing hospitals will be targeted. Therefore, we clarified that hospitals with outlier values indicating specifically poor scores on a measure (for example, a long median time to fibrinolysis) will be targeted for validation. In other words, an “outlier value” is a measure value that is greater than 5 standard deviations from the mean of the measure values for other hospitals, and indicates a poor score.
Comment: One commenter recommended that CMS target hospitals for validation whether their score is greater than five standard deviations above or below the mean, noting that very good scores may especially indicate a need for validation.

Response: The intent of this policy is to target and prevent extreme negative values rather than to identify high performance. This is also evidenced in the first of our two criteria for targeting hospitals for validation—to target hospitals that fail the validation requirement that applies to the previous year’s payment determination. We believe it is appropriate to specifically target hospitals with poor performance, rather than those performing well to encourage improved performance among low performing hospitals. We note that only 50 hospitals will be selected for validation through these targeting criteria and in order to address the issue of very low performance, we believe it is appropriate to use these targeting criteria to identify extreme negative measure values. An additional 450 hospitals will be selected at random, and will include both low and high performing hospitals. However, we thank the commenter for their feedback that extremely high performance could indicate a need for validation, and will take this into consideration as we craft future policies.
**Codification**

We note that the previously finalized procedures for targeting hospitals for validation, described in section XIII.D.7.a. of this final rule with comment period, and finalized in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74485), are not yet codified at 42 CFR 419.46. We proposed to codify the previously finalized procedures for targeting hospitals and well as the procedures regarding outlier hospitals as discussed and clarified above at 42 CFR 419.46(e)(3). We invited public comment on our proposal to codify our validation targeting criteria as discussed above.

We did not receive any public comments on this proposal. Therefore, we are finalizing our proposal to codify the previously finalized procedures for targeting hospitals and well as the procedures regarding outlier hospitals as discussed and clarified above at 42 CFR 419.46(e)(3), as proposed.
Formalization and Modifications to the Educational Review Process for Chart-Abstracted Measures Validation

In an effort to streamline this process, we proposed to:

1. Formalize this process
2. Specify that if the results of an educational review indicate that we incorrectly scored a hospital’s medical records selected for validation, the corrected quarterly validation score would be used to compute the hospital’s final validation score at the end of the calendar year.

These proposals are discussed in more detail below:

Educational Review Process for the CY 2020 Payment Determination and Subsequent Years

Formalizing the Educational Review Process

As stated above, our informal processes for educational review have been described on the QualityNet Web site. Under the informal process, hospitals that were selected and received a score for validation may request an educational review in order to better understand the results. Many times, hospitals request an educational review to examine any data element discrepancies, if they believe the score is incorrect, or when they have general questions about their score. Currently, hospitals receive validation results on a quarterly basis and can request informal educational reviews for each quarter. Under this informal process, a hospital has 30 calendar days from the date the validation results are posted on the QualityNet Secure Portal Web site to contact the CMS designated contractor, currently known as the Validation Support Contractor (VSC), to request an educational review. In response to a request, the VSC obtains and reviews medical records directly from the Clinical Data Abstraction Center (CDAC) and provides feedback. CMS, or its contractor, generally provides educational review results and responses via a secure file transfer to the hospital.

We proposed to formalize this educational review process, as described above, for the CY 2020 payment determination and subsequent years—in other words, starting for validations of CY 2018 data affecting the CY 2020 payment determination and subsequent years.
We invited public comment on our proposal to formalize the chart abstracted measures validation educational review process for the CY 2020 payment determination and subsequent years as described above.

We did not receive any public comments on our proposal. Therefore, we are finalizing the proposal to formalize the chart-abstracted measures validation educational review process for the CY 2020 payment determination and subsequent years, as proposed.

Validation Score Review and Correction

We previously finalized, in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72105 to 72106), that we calculate validation scores under the Hospital OQR Program using the upper bound of a one-tailed confidence interval (CI) with a 75 percent threshold level with a binomial approach. Using that approach, at the end of each calendar year, CMS computes a CI using the results of all four quarters to determine the final validation score. If the upper bound of this confidence interval is 75 percent or higher, the hospital will pass the Hospital OQR Program validation requirement.

We proposed that if the results of a validation educational review determine that the original quarterly validation score was incorrect, the corrected score would be used to compute the final validation score and CI at the end of each calendar year. To determine whether a quarterly validation score was correct, in the CY 2018 OPPS/ASC proposed rule (82 FR 33683), we proposed to use a similar process as one previously finalized for reconsideration requests. Specifically, we proposed that during an educational review request, evaluating a validation score would consist of and be limited to reviewing data elements that were labeled as mismatched (between the originally calculated measure score and the measure score calculated in validation) in the original validation results. We would also take into consideration written justifications provided by hospitals in the Educational Review request.

For more information about the previously finalized reconsideration request procedures, we refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68487 through 68489), the CY 2014 OPPS/ASC final rule with comment period (78 FR 75118 through 75119), the CY 2016 OPPS/ASC final rule with comment period (80 FR 70524), and the CY 2017 OPPS/ASC final rule with comment period (81 FR 79795). For the CY 2020 payment
determination and subsequent years, we further proposed that if an educational review requested for any of the first 3 quarters of validation yields incorrect CMS validation results for chart abstracted measures, according to the review process described above, we would use the corrected quarterly score, as recalculated during the educational review process, to compute the final CI at the end of the calendar year.

We note that for the last quarter of validation, because of the need to calculate the confidence interval in a timely manner and the insufficient time available to conduct educational reviews prior to the annual payment update, the validation score review and correction would not be available. Instead, the existing reconsideration process would be used to dispute any unsatisfactory validation result. We refer readers to section XIII.D.9. of this final rule with comment period for a discussion about our reconsideration and appeals process. The corrected scores would be applicable to the corresponding quarter, for the first 3 quarters of validation, for which a request was submitted. Under this proposal, after evaluating the validation score during the educational review process, if results show that there was indeed an error in the originally calculated score, we would take steps to correct it. However, so as not to dissuade participation in the educational review process, corrected scores identified through the educational review would only be used to recalculate the CI if they indicate that the hospital performed more favorably than previously determined. If the hospital performed less favorably, their score would not be updated to reflect the less favorable score.

We note that under this proposal, the quarterly validation reports issued to hospitals would not be updated to reflect the corrected score due to the burden associated with reissuing corrected reports. However, the corrected score would be communicated to the hospital via secure file format as discussed above.

We invited public comment on our proposal, as discussed above for the CY 2020 payment determination and subsequent years, to use corrected quarterly scores, as recalculated during the educational review process described and finalized in section XIII.D.7.c.(2)(a) of this final rule with comment period above, to compute the final confidence interval for the first 3 quarters of validation.
Comment: Several commenters supported the proposed changes to use the educational review process to correct validation scores, noting that the policy will increase efficiency and help hospitals understand their annual validation score. One commenter recommended that CMS accept educational review requests from facilities that have a passing validation score, given that there could be errors that result in a mistakenly low, though still passing, score.

Response: We thank the commenters for their support and note that under the formalized process we are finalizing, hospitals may request an educational review to examine any data element discrepancies, if they believe the score is incorrect, or when they have general questions about their score (82 FR 33682). Under this process, hospitals receive validation results on a quarterly basis and can request informal educational reviews for each quarter. A hospital has 30 calendar days from the date the validation results are posted on the QualityNet Secure Portal Web site to contact the CMS designated contractor, currently known as the Validation Support Contractor (VSC), to request an educational review.

To be clear, educational review requests are not limited to hospitals that fail validation; any hospital that receives validation results (pass or fail) may request a validation educational review.

After consideration of the public comments received, we are finalizing our proposal to use corrected quarterly scores, as recalculated during the educational review process described in section XIII.D.7.c.(2)(a) of this final rule with comment period above, to compute the final confidence interval for the first 3 quarters of validation for the CY 2020 payment determination and subsequent years, as proposed.