CMS ISSUES PROPOSED MEDICARE PFS RULE FOR CY 2019

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U.S. Health Care Alert

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On July 27, 2018, the Medicare Physician Fee Schedule (PFS) Proposed Rule for Calendar Year (CY) 2019 (PFS Proposed Rule) was published in the Federal Register. [1] The PFS Proposed Rule contains a number of significant proposals, including:

- implementing amendments to the Stark Law regulations consistent with statutory changes related to the writing and signature requirements;
- plans to expand access to telehealth services;
- setting the payment rate under Section 603 of the Bipartisan Budget Act of 2015 for non-excepted items and service for CY 2019;
- reducing payments for drugs acquired under the 340B program that are furnished in non-excepted hospital outpatient provider-based departments; and
- streamlining documentation requirements for evaluation and management (E/M) visits and changing payment guidelines for the visits.

Moreover, the PFS Proposed Rule includes an update to the Quality Payment Program (QPP). The Centers for Medicare & Medicaid Services (CMS) is also proposing changes related to the definition of “applicable laboratories” for purposes of the rules requiring reporting of private payor rates and is soliciting additional comments in this area, as well as in regard to pricing transparency. If finalized, the PFS Proposed Rule would become effective on January 1, 2019. Comments are due no later than 5 p.m. on September 10, 2018.

We have highlighted some key aspects of the PFS Proposed Rule below and plan to follow up with additional detail in subsequent alerts on a number of these areas.

PHYSICIAN SELF-REFERRAL LAW

CMS proposes amendments to the Stark Law regulations consistent with Stark Law statutory amendments related to the writing and signature requirements that were enacted as part of the Bipartisan Budget Act of 2018.

- a new special rule on compensation arrangements at 42 C.F.R. § 411.354(e) to explicitly permit that, for any compensation arrangement that is required to be in writing, the writing requirement may be satisfied

by a collection of documents, including contemporaneous documents evidencing the course of conduct between the parties; and

- modifications to the regulation regarding temporary noncompliance with signature requirements at 42 C.F.R. §411.353(g)(1) to provide that parties have 90 days to obtain signatures whether the lack of a timely signature was advertent or inadvertent, and deletion of the current restriction that the temporary compliance rule could only be used once every three years for a particular physician or physician group. [2]

MODERNIZING MEDICARE PHYSICIAN PAYMENT BY RECOGNIZING COMMUNICATION TECHNOLOGY-BASED SERVICES

CMS proposes to significantly expand access to telehealth services by proposing new communication technology-based services to be eligible for reimbursement. The PFS Proposed Rule distinguishes between Medicare telehealth services, for which reimbursement is quite restricted due to statutory requirements, and "communication technology-based and remote evaluation services," for which the statutory restrictions would not apply. CMS proposes to establish new payment codes in order to reimburse clinicians for virtual check-ins (such as brief non-face-to-face appointments that occur via telecommunications technology) and for professional evaluations of patient-transmitted information conducted via pre-recorded "store and forward" video or image technology. In addition, CMS has proposed expansion of Medicare telehealth services, including the addition of payment for prolonged preventative services and the addition of mobile stroke units as a permissible origination site for acute stroke telehealth services. [3]

PAYMENT RATES UNDER THE MEDICARE PFS FOR NONEXCEPTED ITEMS AND SERVICES FURNISHED BY NONEXCEPTED OFF-CAMPUS PROVIDER-BASED DEPARTMENTS OF A HOSPITAL

CMS proposes largely to continue the CY 2018 payment mechanism and reimbursement amounts for nonexcepted off-campus hospital outpatient provider-based departments (PBD). [4]

Section 603 of the Bipartisan Budget Act of 2015 generally imposed a "site-neutral" payment policy for new PBDs established on or after November 2, 2015, subject to certain exceptions. [5] For CY 2019, CMS notes that it has access to a full year of claims data from CY 2017 for nonexcepted items and services submitted with the "PN" modifier and that incorporating this data allows it to improve the accuracy of the PFS Relativity Adjuster by accounting for the specific mix of nonexcepted items and services furnished in nonexcepted off-campus PBDs. [6] In that regard, in the CY 2019 PFS Proposed Rule, CMS indicates that it has now assessed separately payable items and services, weighted by the number of Healthcare Common Procedure Coding System codes on claims for each service for both PFS and Hospital Outpatient Prospective Payment System (OPPS). [7] In the end, based on its evaluation of that additional data, CMS proposes to continue to allow nonexcepted PBDs to bill for nonexcepted items and services on an institutional claim through OPPS using a "PN" modifier and to continue with the PFS reimbursement amount for those services set at 40 percent of OPPS. [8]

EVALUATION & MANAGEMENT VISITS

CMS proposes several changes to E/M visit documentation and payment guidelines, which would apply primarily to office-based and outpatient visit codes (CPT codes 99201 through 99215). [9] CMS's primary goal in proposing these changes is to reduce administrative burden for practitioners. [10]

- *Documentation*. CMS proposes that practitioners will be able to choose to use one of the following as a basis to determine the appropriate level of the E/M visit:
  a. the "1995" or "1997" E/M Documentation Guidelines, available on the CMS Website;
  b. the medical decision-making component of an E/M visit; or
  c. the time or duration of an E/M visit. [11]
- *Simplified Payment Amounts*. CMS proposes to pay a single rate for level 2 through level 5 E/M visits. [12] CMS proposes developing a set of relative value units (RVUs) under the PFS for E/M visit levels 2 through 5 for new patients (CPT codes 99202 through 99205) and a set of RVUs for E/M visit levels 2 through 5 for existing patients (CPT codes 99212 through 99215). [13] CMS proposes to maintain the current code set in order to avoid the administrative burden of adopting a new code system for practitioners. [14]
- *Corresponding Payment Adjustments*. In addition to proposing a single payment rate for visit levels 2 through 5, CMS also proposes corresponding payment policies and adjustments to account for resource costs associated with E/M visits requiring different types of care. [15]

CMS proposes that the new E/M documentation and visit policies would be effective January 1, 2019. [16]

RADIOLOGIST ASSISTANTS

In accordance with 42 C.F.R. § 410.32(b), unless an exception applies, all diagnostic X-ray and other diagnostic tests are required to be provided under the level of physician supervision specified by CMS, either general, direct, or personal, as those terms are defined in the regulation. For most diagnostic imaging procedures, the required physician supervision level applies only to the technical component of the procedure. CMS proposes to amend § 410.32(b) to specify that any diagnostic tests that would otherwise require personal supervision would only require direct supervision when performed by a registered radiologist assistant who is certified and registered by the American Registry of Radiologic Technologists or a radiology practitioner assistant (RPA) who is certified by the Certification Board for Radiology Practitioner Assistants, as permitted by state law and state scope of practice regulations. [17] Diagnostic imaging tests requiring a general level of physician supervision would still only require general supervision. [18]

THERAPY SERVICES

In accordance with the Bipartisan Budget Act of 2018:

- CMS is repealing the Medicare outpatient therapy caps and the therapy cap exceptions process while retaining and adding limitations to ensure that therapy services are furnished when appropriate. [19]
- Outpatient therapy services (physical therapy and occupational therapy) furnished in whole or in part by a therapy assistant will be reimbursed at a rate of 85 percent of the otherwise applicable Part B payment amount for the service. This reduced payment amount for outpatient therapy services is applicable when payment is made directly under the PFS. [20] To implement this provision, CMS proposes to establish two new modifiers to identify separately physical therapy and occupational therapy services that are furnished in whole or in part by a therapy assistant. [21]

In addition, CMS has indicated that the general consensus of commenters who responded to CMS's Request for Information on burden reductions was that the functional reporting requirements for outpatient therapy services are overly complex and burdensome. [22] In response to the comments, CMS proposes to discontinue the functional reporting requirements for outpatient therapy services furnished on or after January 1, 2019. [23]

PART B DRUGS: APPLICATION OF AN ADD-ON PERCENTAGE FOR CERTAIN WHOLESALE ACQUISITION COST-BASED PAYMENTS

CMS proposes to use a 3 percent add-on in place of the current 6 percent add-on for payments for Part B drugs based on wholesale acquisition cost (WAC) made under Section 1847A(c)(4) of the Social Security Act. [24]

CLINICAL LABORATORY FEE SCHEDULE

CMS implemented revisions to the Clinical Laboratory Fee Schedule (CLFS) in response to Section 216 of the Protecting Access to Medicare Act of 2014 (PAMA), which required that the payment amount for most clinical diagnostic laboratory tests (CDLTs) be equal to the weighted median of private payor rates. [25] Pursuant to regulations promulgated by CMS at 42 C.F.R. 414.500 et seq., an entity must report private payor rates, volume data, and other “applicable information” for each CDLT [26] furnished by each of its components that meets the definition of an “applicable laboratory” every three years. The first round of reporting was required in the first part of 2017, and was used by CMS to set rates under the CLFS beginning January 1, 2018.

As currently defined, the term “applicable laboratory” means an entity that is a laboratory, as defined in 42 C.F.R. § 493.2 of the Clinical Laboratory Improvement Amendments (CLIA) regulations; bills Medicare Part B under its own National Provider Identifier (NPI); and, in the applicable six-month data collection period, meets both the “majority of Medicare revenues threshold” and the “low expenditure threshold.” [27] The majority of Medicare revenues threshold is met if the entity receives, under its NPI, more than 50 percent of its Medicare revenues, which includes fee-for-service payments under Medicare Parts A and B, Medicare Advantage payments under Medicare Part C, prescription drug payments under Medicare Part D, and any associated Medicare beneficiary deductible or coinsurance from the CLFS (42 C.F.R. part 414, subpart G), the CLFS and/or the PFS (42 C.F.R. part 414, subpart B). The low expenditure threshold is met if the entity receives, under its NPI, at least $12,500 of its Medicare revenues from the CLFS for CDLTs that are not advanced diagnostic laboratory tests.

In response to stakeholder feedback noting that the 2018 CLFS payment rates were based on data collected from a relatively small number of applicable laboratories and therefore arguing that the rates were inaccurate, CMS

proposes to make changes to the definition of "applicable laboratory" and is soliciting comments on other proposals that would potentially increase the number of applicable laboratories required to report applicable information. [28] More specifically, CMS proposes to change the calculation of the majority of Medicare revenues threshold by excluding payments made by Medicare Advantage (MA) plans under Medicare Part C from the denominator. [29] The effect of this change would be to permit laboratories that have significant revenues from MA payments to qualify as applicable laboratories, thereby increasing the amount of reported data used to determine CLFS payment rates. [30]

In addition, CMS is seeking comment on the following proposals aimed at increasing or improving the quality of data used to determine CLFS rates:

- *Changes to the Low Expenditure Threshold*. In order to increase the number of "applicable laboratories," CMS proposes to decrease the low expenditure threshold by 50 percent, from $12,500.00 to $6,250.00. [31] CMS is soliciting comments on the administrative burden this would pose to small physician practices and small independent clinical laboratories that may have previously been exempt from reporting. [32] As an alternative approach, CMS is seeking comments on the potential impact of increasing the low expenditure threshold by 50 percent, from $12,500.00 to $18,750.00. [33] While this may reduce the volume of "applicable laboratories," CMS notes that an increase in the threshold may reduce administrative burden on small physician practices and independent laboratories which may otherwise be required to track and report private payor data. [34]
- *Using Form CMS-1450 Bill Type 14x to Determine Majority of Medicare Revenues and Low Expenditure Thresholds.* As currently defined, an applicable laboratory is, in part, an entity that bills under its own NPI. [35] Because many hospital outreach laboratories bill under the NPI of the hospital, rather than their own NPI, CMS is seeking comments on an alternate approach, which would increase the number of applicable laboratories by including more hospital outreach laboratories. Specifically, hospital outreach laboratories would determine whether they meet the requirements to be considered an "applicable laboratory" using only revenues for services reported under bill type 14x on the Form CMS-1450, rather than using all Medicare revenues reported under the NPI used on the bills. [36] Bill type 14x is used for hospital laboratory services provided to non-patients. CMS expresses its concerns that this approach would present operational issues for hospitals as well as potentially be inconsistent with statutory authority, based in part on CMS's view that this change would result in all hospital outreach laboratories meeting the definition of applicable laboratories. [37]
- *Using CLIA Certificates to Define Applicable Laboratories*. Finally, while CMS expresses concern that not all entities that meet the CLIA regulatory definition at 42 C.F.R. § 493.2 should be considered "applicable laboratories," in response to stakeholder requests, CMS is seeking comments on the potential impact of defining applicable laboratory to include any laboratory with a CLIA certificate rather than by NPI. [38] CMS notes that a CLIA certificate-based definition of "applicable laboratory" would be overly broad, capturing all hospital laboratories, rather than just hospital outreach laboratories. [39] Moreover, CMS points out that CLIA certification is meant to demonstrate a laboratory's compliance with applicable health and safety regulations, and unlike the NPI, is not associated with Medicare billing. [40] It is not included on the Form CMS-1450, raising the question of how a hospital would identify revenues by CLIA certificate in order to determine if the applicable laboratory definition is met. [41]

PAYMENT FOR CARE MANAGEMENT SERVICES AND COMMUNICATION TECHNOLOGY-BASED SERVICES IN RURAL HEALTH CLINICS AND FEDERALLY QUALIFIED HEALTH CENTERS

For Rural Health Centers (RHCs) and Federally Qualified Health Centers (FQHCs), CMS has proposed to revise the payment methodology for the general care management code and to establish separate payment to RHCs and FQHCs for certain communication technology-based services and remote evaluation services not currently captured in the RHC all-inclusive rate or the FQHC prospective payment systems when the requirements for such services are met. [42]

APPROPRIATE USE CRITERIA FOR ADVANCED DIAGNOSTIC IMAGING SERVICES

Pursuant to Section 218(b) of PAMA, [43] in its CY 2016 PFS final rule CMS developed a program requiring physicians and practitioners to consult certain appropriate use criteria (AUC) when ordering advanced diagnostic imaging services in certain settings. [44]

- The services covered by this program include:
  - diagnostic magnetic resonance imaging, computed tomography, nuclear medicine (including positron emission tomography), and other diagnostic imaging services specified by CMS in consultation with the medical community and stakeholders, but excluding x-ray, ultrasound, and fluoroscopy services. [45]
- The program is set to be implemented January 1, 2020, though providers may begin reporting on a voluntary basis as of July 2018. [46]

In the PFS Proposed Rule, CMS provides some additional clarity to the AUC requirements. Particularly, CMS clarifies that:

- independent diagnostic testing facilities are applicable settings which require AUC consultation and reporting; [47]
- AUC consultation may be performed by clinical staff working under the direction of the ordering professional and incident to the ordering professional's services rather than by the ordering professional alone; [48]
- AUC consultation must be reported on all claims for applicable imaging services, including both the professional and facility claims; [49]
- providers may report AUC information on claims using established coding methods, including certain G-codes and modifiers; [50] and
- changes to the significant hardship exception include insufficient internet access, electronic health record (EHR) or clinical decision support mechanism vendor issues, or extreme and uncontrollable circumstances. [51]

CMS has requested comments on these proposals, as well as comments related to the identification of outlier ordering professionals. [52]

MEDICAID PROMOTING INTEROPERABILITY PROGRAM REQUIREMENTS FOR ELIGIBLE PROFESSIONALS

CMS proposes to amend the list of available electronic clinical quality measures (eCQMs) for the CY 2019 performance period. [53] CMS proposes to align the eCQMs available for Medicaid Eligible Professionals (EPs) in 2019 with those available for Merit-Based Incentive Payment System (MIPS) eligible clinicians for the CY 2019 performance period, so the eCQMs available for Medicaid EPs in 2019 would consist of the list of quality measures available under the eCQM collection type on the final list of quality measures established under MIPS for the CY 2019 performance period. [54] CMS believes this change is responsive to stakeholder feedback and would reduce the burden on Medicaid EPs. [55]

- CMS also requests comment on whether it should include all e-specified measures from the core set of quality measures for Medicaid and the Children's Health Insurance Program and the core set of health care quality measures for adults enrolled in Medicaid as additional options for Medicaid EPs. [56] Some of these measures are already included in the MIPS eCQM list, but some are not. [57]
- CMS proposes for CY 2019 that Medicaid EPs would report on any six eCQMs that are relevant to the EP's scope of practice, either via attestation or electronically. [58]
- Further, CMS proposes that EPs report on at least one outcome measure (or, if an applicable outcome measure is not available or relevant, one other high priority measure). [59]
- CMS proposes that the eCQM reporting period for EPs in the Medicaid Promoting Interoperability Program would be a full CY in 2019 for EPs who have demonstrated meaningful use in a prior year, in order to align with the corresponding performance period in MIPS for the quality performance category. [60]
- Additionally, CMS proposes that the EHR reporting period in 2021 for all EPs in the Medicaid Promoting Interoperability Program would be a minimum of any continuous 90-day period within CY 2021, provided that the end date for this period falls before October 31, 2021. [61]
- Based on feedback, CMS proposes to change the thresholds for Measure 1 (View, Download, or Transmit) and Measure 2 (Secure Electronic Messaging) of Meaningful Use Stage 3 EP Objective 6 (Coordination of Care through Patient Engagement) so that it will remain at 5 percent for 2019 and subsequent years. [62]
- For EP Objective 8 (Public health and clinical data registry reporting) and Measure 2 (Syndromic surveillance reporting measure), CMS proposes to include any EP defined by the state or local public health agency as a provider who can submit syndromic surveillance data. [63]

CY 2019 UPDATES TO QUALITY PAYMENT PROGRAM

The PFS Proposed Rule introduces a number of payment and policies changes to the QPP as part of QPP's third implementation year. The changes cover a wide range of topics, many geared toward continuing the multi-year transition toward a fully-implemented program. In addition to numerous annual changes to scoring measures and methodology updates, a few highlights of the proposed changes are as follows:

- Highlighted Changes to the MIPS:
  - Changing the "low-volume threshold" definition, notably adding a new criterion, starting in MIPS payment year 2021, allowing clinicians or groups to fall within this threshold if they provide 200 or fewer covered professional services to Part B-enrolled individuals in a year. [64]
  - Modifying the timing and process for how CMS will determine whether a "virtual group" is eligible to participate in MIPS. [65]
  - Changing the terminology used to describe the data submission process by MIPS eligible clinicians, groups, and third-party intermediaries with a goal of more accurately describing the real-world data submission experience, through the inclusion of the new terms "collection type," "submitter type," and "submission type." [66]
  - Renaming the existing "Advancing Care Information" performance category to "Promoting Interoperability" (PI), to better highlight CMS's goals for the category. [67]
  - Removing the "CMS Web Interface" submission type as an option for groups submitting data for the Improvement Activities or PI categories and limiting the "Medicare Part B claims" submission type as an option available to small practices only. [68]
  - Establishing a revised final score performance category weight starting in MIPS payment year 2021, with the Quality category making up 45 percent of the final score, Cost making up 15 percent, Improvement Activities making up 15 percent, and PI making up 25 percent. [69]
  - Increasing the "performance threshold" (the point at which a clinician will not incur a payment reduction under MIPS) from 15 to 30 points out of a total of 100 for MIPS payment year 2021, and acknowledging that the performance threshold is expected to continue to rise to between approximately 63.50 and 69 points by MIPS payment year 2024. [70]
  - Setting the "additional performance threshold" (the point at which a clinician is eligible for sharing in $500,000,000 of additional incentive funding) at 80 points for MIPS payment year 2021. [71]
  - Making several changes to the definitions and requirements for third-party intermediaries participating in MIPS, largely geared toward the nomination and certification process for Qualified Clinical Data Registries. [72]
- Highlighted Changes to the Advanced Alternative Payment Model ("Advanced APM") Incentive:
  - Increasing the certified EHR technology (CEHRT) threshold for an APM to qualify as an Advanced APM, requiring at least 75 percent of eligible clinicians participating in an Advanced APM to use CERHT starting in calendar year 2019, up from the current threshold of 50 percent. [73]

- Proposing to maintain the current financial risk threshold requirement for Advanced APMs at 8 percent of average estimated total Medicare Parts A and B revenue for performance periods 2021 through 2024 (backtracking from prior proposals to increase the threshold requirement). [74]
- Providing additional flexibility to payors and providers to demonstrate CEHRT use under the "Other Payer Advanced APM" criteria; specifically, by not requiring an express agreement between payers and providers that 75 percent of clinicians are using CEHRT, as long as the parties can otherwise demonstrate to CMS that the threshold is met in practice. [75]
- Introducing details on how commercial and other private payers can request a determination about whether their payor arrangements will qualify as an "Other Payer Advanced APMs," starting with the 2020 performance period. In particular, CMS notes that it intends to make detailed guidance on this process available to providers in January 2019. [76]

REQUEST FOR INFORMATION ON PROMOTING INTEROPERABILITY AND ELECTRONIC HEALTHCARE INFORMATION EXCHANGE THROUGH POSSIBLE REVISIONS TO THE CMS PATIENT HEALTH AND SAFETY REQUIREMENTS FOR HOSPITALS AND OTHER MEDICARE- AND MEDICAID-PARTICIPATING PROVIDERS AND SUPPLIERS

While CMS recognizes the high rate of adoption of CEHRT, barriers still exist for the exchange of electronic health information across the continuum of care. [77] Several new initiatives related to electronic exchange of health information will be implemented over the next few years.

- For example, through the 21st Century Cures Act, Congress has directed that the Office of the National Coordinator for Health Information Technology (ONC), "…for the purpose of ensuring full network-to-network exchange of health information, convene public-private and public-public partnerships to build consensus and develop or support a trusted exchange framework, including a common agreement among health information networks nationally." [78]
    - In January 2018, ONC released a draft version of its proposal for the Trusted Exchange Framework and Common Agreement, which establishes minimum standards for trusted exchange to enable interoperability across disparate health information networks. ONC will finalize the Trusted Exchange Framework based on public comments and release a final version. [79]

In light of the widespread adoption of EHR, CMS is interested in hearing about how it can use the Conditions of Participation (CoPs), Conditions for Coverage (CfCs), and Requirements for Participation (RfPs) for Long-Term Care (LTC) Facilities to advance the electronic exchange of health information among providers to facilitate safe transitions of care as well as to ensure patients and caregivers have access to health information. [80] CMS noted several proposed and final rules that also address such communication among providers; a proposed rule (80 FR 68126) to implement the provisions of the Improving Medicare Post-Acute Care Transformation Act of 2014 (the IMPACT Act) (Pub. L. 113-185); a proposed rule (81 FR 39448) that updated a number of CoPs requirements that hospitals and critical access hospitals would need to meet in order to participate in the Medicare and Medicaid

programs; and a final rule (81 FR 68688) that revised the requirements that LTC facilities must meet to participate in the Medicare and Medicaid programs. [81]

CMS presented several specific questions, for which it requested feedback, including the following:

- Do stakeholders believe that new or revised CMS CoPs/CfCs/RfPs for interoperability and electronic exchange of health information would help improve routine electronic transfer of health information as well as overall patient/resident care and safety? [82]
- Should CMS propose new CoPs/CfCs/RfPs for hospitals and other participating providers and suppliers to ensure a patient's or resident's (or his or her caregiver's or representative's) right and ability to electronically access his or her health information without undue burden? Would existing portals or other electronic means currently in use by many hospitals satisfy such a requirement regarding patient/resident access as well as interoperability? [83]
- Are new or revised CMS CoPs/CfCs/RfPs for interoperability and electronic exchange of health information necessary to ensure patients/residents and their treating providers routinely receive relevant electronic health information from hospitals on a timely basis or will this goal be achieved anyway in the next few years through existing Medicare and Medicaid policies, the implementing regulations related to the privacy and security standards of the Health Insurance Portability and Accountability Act of 1996 (Pub. L. 104-91), and implementation of relevant policies in the 21st Century Cures Act? [84]
- What would be a reasonable implementation timeframe for compliance with new or revised CMS CoPs/CfCs/RfPs for interoperability and electronic exchange of health information? Should these requirements have delayed implementation dates for specific participating providers and suppliers, or types of participating providers and suppliers (for example, participating providers and suppliers that are not eligible for the Medicare and Medicaid EHR Incentive Programs)? [85]

CMS is also interested in comments on how to advance the Federal Government's MyHealthEData initiative, which is aimed at giving patients control of their medical data. [86]

REQUEST FOR INFORMATION ON PRICE TRANSPARENCY: IMPROVING BENEFICIARY ACCESS TO PROVIDER AND SUPPLIER CHARGE INFORMATION

CMS is soliciting comments on price transparency to improve beneficiary access to provider and supplier charge information. The Affordable Care Act requires that each hospital operating within the United States, for each year, establish, update, and make public a list of the hospital's standard charges for items and services provided by the hospital, including for diagnosis-related groups. To comply with this requirement, CMS has previously issued guidelines to hospitals to make public either a list of their standard charges (whether that be the chargemaster itself or in another form of their choice) or their policies for allowing the public to view a list of those charges in response to an inquiry. In the Fiscal Year 2019 Inpatient Prospective Payment System/Long-Term Care Hospital Proposed Rule, CMS proposed to update its guidelines, so that, effective January 1, 2019, hospitals will be required to make public a list of their standard charges on the internet in a machine-readable format. This list would be required to be updated at least annually, or more often as appropriate. [87]

In the PFS Proposed Rule, CMS continues to note its concern that patients may be surprised by unexpected bills, such as for out-of-network physician services at in-network facilities, for facility fees, and for physician services in emergency departments. CMS also expresses its concern that charge information may not adequately assist patients in understanding what they are likely to owe for services rendered. [88] Therefore, CMS is considering ways to improve the accessibility and usability of charge information for patients and is considering potential actions that would facilitate consumer-friendly communication by providers and suppliers of their charges. To that end, CMS is soliciting comments in a number of areas, such as:

- The definition of "standard charges" across various provider and supplier settings, what the definition should be based on, and whether it should be different depending on whether or not the setting maintains a chargemaster.
- The types of information most beneficial to patients, how providers and suppliers can best enable patients to use charge and cost information in their decision-making, and how CMS, providers and suppliers can help third parties create patient-friendly interfaces with this data.
- Whether providers and suppliers should be required to inform patients of the out-of- pocket costs for a service before the service is rendered and how that information would be provided to better support patient choice and decision-making.
- How CMS can help beneficiaries better understand their Medicare cost-sharing obligations for each Medicare-covered service and what role providers and suppliers should play in helping inform patients of their out-of-pocket costs.
- Whether CMS can require providers and suppliers to inform patients of Medicare reimbursement for particular services performed by that provider or supplier and, if so, what changes would need to be made by providers and suppliers and what burdens would be imposed as a result.

CMS is also seeking comments in similar areas on improving Medigap patients' understanding of their out-of-pocket costs prior to receiving services. [89]

Notes:
[1] Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; and Medicaid Promoting Interoperability Program, 83 Fed. Reg. 35,704 (proposed July 27, 2018).
[2] *Id*. at 35,879-80, 36,072-73.
[3] *See id*. at 35,722-731, 36,072-073.
[4] *Id*. at 35,704, 35,740.
[5] Pub. L. No. 114–74.
[6] *Id*. at 35,740.
[7] *Id*.
[8] *Id*.
[9] *Id*. at 35,834-35.
[10] *Id*. at 35,838.

[11] *Id*. at 35,836. For the 1995 or 1997 E/M Documentation Guidelines, see: https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/eval-mgmt-serv-guide-ICN006764.pdf.
[12] 83 Fed. Reg. at 35,839.
[13] *Id*.
[14] *Id*.
[15] *Id*. at 35,840.
[16] *Id*. at 35,848.
[17] *See id*. at 35,738, 36,072.
[18] *Id*. at 35,738
[19] *Id*. at 35,850.
[20] *Id*.
[21] *Id*.
[22] *Id*. at 35,853.
[23] *Id*.
[24] *Id*.
[25] Pub. L. 113-93, § 216, 128 Stat. at 1054-55.
[26] The requirements are different as to advanced diagnostic laboratory tests. This summary only addresses CDLTs.
[27] 42 C.F.R. § 414.502.
[28] *See* 83 Fed. Reg. at 35,856.
[29] *See id.* at 35,857.
[30] *See id*.
[31] *See id*. at 35,849, 35,860-1.
[32] *See id*.
[33] *See id*. at 35,849, 35,861.
[34] *See id*.
[35] See 42 C.F.R. § 414.502.
[36] See 83 Fed. Reg. at 35,859.
[37] *See id.* at 35,859-60.
[38] *See id.* at 35,860.
[39] *See id.*
[40] *See id*.
[41] *See id*.
[42] *See id*. at 35,863-64, 36,072.
[43] Pub. L. No. 113-93, § 218(b), 128 Stat. 1040, 1065 (2014).
[44] See Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016, 80 Fed. Reg. 70,886, 71,102–71,116 (Nov. 16, 2015). Under the program, AUC requirements are not applicable in the following circumstances: (1) services ordered for an individual with an emergency medical condition; (2) services ordered for an inpatient for which payment is made under Part A; (3) services ordered by an ordering professional who is granted a significant hardship exception. See 83 Fed. Reg. at 35,867.
[45] 80 Fed. Reg. at 71,103.

[46] 83 Fed. Reg. at 35,865.
[47] *Id*. at 35,867 (in addition to existing applicable settings, including physicians' offices, hospital outpatient departments (including emergency departments), ambulatory surgery centers, and any other provider-led outpatient settings as determined to be appropriate by the Secretary).
[48] *Id*. at 35,868.
[49] *Id*.
[50] *Id*. at 35,869.
[51] *Id*.
[52] *Id*. at 35,870.
[53] *Id*. at 35,871.
[54] *Id*.
[55] *Id*.
[56] *Id*.
[57] *Id*.
[58] *Id*. at 35,872.
[59] *Id*.
[60] *Id*.
[61] *Id*. at 35,873.
[62] *Id*.
[63] *Id*. at 35,874.
[64] *Id*. at 35,887
[65] *Id*. at 35,891.
[66] *Id*. at 35,893.
[67] *Id*. at 35,912.
[68] *Id*. at 35,894.
[69] *Id*. at 35,965.
[70] *Id*. at 35,971.
[71] *Id*. at 35,973.
[72] *Id*. at 35,981–85.
[73] *Id*. at 35,990.
[74] *Id*. at 35,991–92.
[75] *Id*. at 35,997.
[76] *Id*. at 36,000–01.
[77] *Id*. at 36,006.
[78] *Id*. at 36,007.
[79] *Id*.
[80] *Id*.
[81] *Id*. at 36,007-08.
[82] *Id*. at 36,008.
[83] *Id*.
[84] *Id*.
[85] *Id*.

[86] *Id*.
[87] *See id*. at 36,009.
[88] *Id*.
[89] *See id*. at 36,009-10.

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