CMS ISSUES FINAL MEDICARE PFS RULE FOR CY 2019

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Health Care Alert

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On November 1, 2018, the Centers for Medicare and Medicaid Services (CMS) released in pre-publication form the Medicare Physician Fee Schedule (PFS) Final Rule for Calendar Year (CY) 2019 (PFS Final Rule) [1]. The PFS Final Rule contains a number of significant changes, including:

- providing for reimbursement for communication technology-based services and expanding access to telehealth services by allowing for reimbursement for acute stroke telehealth services;
- streamlining requirements for evaluation and management (E/M) visits to reduce administrative and regulatory burden associated with documentation of the visits and changing payment guidelines to create a single payment rate for levels 2 through 4 visits;
- establishing a payment methodology for the general care management services for Rural Health Centers (RHCs) and Federally Qualified Health Centers (FQHCs);
- aligning the electronic clinical quality measures (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;
- implementing amendments to the Stark Law regulations consistent with statutory changes related to the writing and signature requirements;
- updating the CMS Quality Payment Program (QPP); and
changing the definition of “applicable laboratories” for purposes of the rules requiring reporting of private payor rates.

We provide below a full summary of each of the key changes noted above and provide other highlights from the PFS Final Rule. The PFS Final Rule is scheduled to be published in the Federal Register on November 23, 2018. A link to our prior alert on the PFS Proposed Rule is provided here.

MODERNIZING MEDICARE PHYSICIAN PAYMENT BY RECOGNIZING COMMUNICATION TECHNOLOGY-BASED SERVICES

CMS finalized its proposals to establish new payment codes to reimburse clinicians for certain technology-based services under specified conditions, including:

- Healthcare Common Procedure Coding System (HCPCS) code G2012, for brief communication technology-based services, such as brief non-face-to-face virtual check-ins that occur via telecommunications technology (including audio-only communications) if certain requirements are met;
- HCPCS code G2010 to make separate payment for remote evaluation of recorded video and/or images submitted by an established patient; and
- separate payment for interprofessional consultation CPT codes 99451, 99452, 99446, 99447, 99448, and 99449, which describe assessment and management services conducted through telephone, internet, or electronic health record consultations furnished when a patient's treating physician or other qualified health care professional requests the opinion and/or treatment advice of a consulting physician or qualified health care professional with specific specialty expertise to assist with the diagnosis and/or management of the patient's problem without the need for the patient's face-to-face contact with the consulting physician or qualified health care professional.

CMS specifically emphasized the importance of notifying patients of their cost-sharing obligations related to these remote services (which CMS stated it does not have the authority to waive), despite any potential burden on clinicians. Accordingly, clinicians must obtain patient consent, which must be documented in the medical record, each time such remote services are provided.

In addition, in order to implement the requirements of section 50325 of the Bipartisan Budget Act of 2018, CMS finalized a new modifier to identify acute stroke telehealth services and revisions to 42 C.F.R. § 410.78 and § 414.65 to allow for reimbursement for acute stroke telehealth services, including a definition of “mobile stroke unit” and the addition of a mobile stroke unit as a permissible originating site for such acute stroke telehealth services [2].

INTERIM FINAL RULE EXPANDING THE USE OF TELEHEALTH SERVICES FOR THE TREATMENT OF OPIOID USE DISORDER AND OTHER SUBSTANCE USE DISORDERS UNDER THE SUBSTANCE USE-DISORDER PREVENTION THAT PROMOTES OPIOID RECOVERY AND TREATMENT FOR PATIENTS AND COMMUNITIES ACT

Section 2001(a) of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act [3] (SUPPORT Act) amended Section 1834(m) of the Social Security Act to remove the originating site geographic requirements for telehealth services furnished on or after July 1, 2019, for the purpose of treating individuals diagnosed with a substance use disorder or a co-occurring mental health disorder (with the exception of a renal dialysis facility), add an individual's home as a permissible originating site for these telehealth services, and require that no originating site facility fee be paid in instances when the individual's home is the originating site. In addition, Section 2005 of the SUPPORT Act establishes a new Medicare benefit category for opioid use disorder treatment services furnished by Opioid Treatment Programs (OTPs) under Medicare Part B, beginning on or after January 1, 2020, which requires that opioid use disorder treatment services include Food and Drug Administration (FDA) approved opioid agonist and antagonist treatment medications, the dispensing and administration of such medications (if applicable), substance use disorder

counseling, individual and group therapy, toxicology testing, and other services determined appropriate (but not meals and transportation). Section 2005 defines OTPs as those that enroll in Medicare and are certified by the Substance Abuse and Mental Health Services Administration (SAMHSA), accredited by a SAMHSA-approved entity, and meeting additional conditions as the Secretary finds necessary to ensure the health and safety of individuals being furnished services under these programs and the effective and efficient furnishing of such services. [4]

In order to implement the requirements of Section 2001(a) of the SUPPORT Act, CMS has issued an interim final rule with comment period revising several Medicare telehealth regulations. There is a 60-day period following publication of the interim final rule for the public to comment on these interim final amendments to the regulations and to respond to CMS's request for information regarding services furnished by OTPs, payments for these services, and additional conditions for Medicare participation for OTPs that stakeholders believe may be useful to consider for future rulemaking to implement this new Medicare benefit category. In addition, CMS is requesting as part of this interim final rule additional information from stakeholders and the public that might be considered for future rulemaking regarding payment structure and amounts for substance abuse disorder (SUD) treatment that account for ongoing treatment and wide variability in patient needs for treatment of SUDs while improving access to necessary care. [5]

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

In the PFS Final Rule, CMS finalized its proposal to continue the CY 2018 payment mechanism and reimbursement amounts for nonexcepted off-campus hospital outpatient provider-based departments (PBDs). In particular, CMS will continue to allow nonexcepted off-campus PBDs to bill for nonexcepted items and services on institutional claims with a “PN” modifier, which will be used “until we identify a workable alternative mechanism to improve payment accuracy.” [6] CMS will also continue to pay with the PFS reimbursement amount for such services set at 40% of OPPS — i.e., the PFS Relativity Adjuster. In calculating this PFS Relativity Adjuster, CMS stated that its analysis supports maintaining an adjustment of 40% for CY 2019 and beyond “until there is an appropriate reason and process for implementing an alternative to our policy.” [7] In setting the rate, CMS rejected the arguments of commenters who wrote that a rate of 65–70% would be more appropriate. [8]

EVALUATION AND MANAGEMENT VISITS

CMS finalized several changes to E/M visit documentation and payment guidelines, which will apply primarily to office-based and outpatient visit codes. [9] These changes are part of CMS's ongoing effort to reduce the regulatory burden associated with E/M coding and payment. [10]

Documentation

CMS's E/M Documentation Guidelines set forth the medical information required to support an E/M visit in three categories: history of present illness, physical examination, and medical decision-making. [11] Practitioners

currently may choose to use one of two versions of the E/M Documentation Guidelines, the “1995” or the “1997” guidelines, to support a level 1 through 5 E/M visit. [12] In an effort to reduce administrative burden, CMS finalized new documentation options to promote flexibility regarding the documentation required for E/M visits. [13] Effective January 1, 2021, practitioners will be able to choose among the following documentation methodologies to support E/M level 2 through 4 visits:

1. the current “1995” or “1997” E/M Documentation Guidelines, sufficient to support a level 2 E/M visit;
2. the medical decision-making component of an E/M visit alone, sufficient to support a level 2 E/M visit under the 1995 or 1997 E/M Documentation Guidelines; or
3. the total amount of face-to-face time or duration of an E/M visit alone, documenting that the practitioner personally spent the current typical time associated with the CPT code reported on the claim. [14]

Simplified Payment Amounts

In the PFS Proposed Rule, [15] CMS proposed to pay a single rate for level 2 through level 5 E/M visits by developing sets of relative value units (RVUs) under the PFS for new patients and existing patients. [16] CMS received comments that the proposed single payment rate would not adequately account for the amount of resources required to treat the most complex patients. [17] In response, CMS instead finalized a single payment rate for E/M visit levels 2 through 4, developing a set of RVUs under the PFS for E/M visit levels 2 through 4 for new patients (CPT codes 99202 through 99204) and a set of RVUs for E/M visit levels 2 through 4 for existing patients (CPT codes 99212 through 99214). [18] CMS will maintain separate payment rates for new and established patients for E/M levels 1 and 5 visits. [19] In addition, in response to commenters' concerns regarding the timing of such change, CMS delayed the effective date of the single payment rate for levels 2 through 4 E/M visits, which will not become effective until January 1, 2021. [20]

Corresponding Payment Adjustments

In addition to finalizing a single payment rate for visit levels 2 through 4, CMS also accounted for resource costs associated with certain E/M level 2 through 4 visits requiring different types of care by finalizing two corresponding payment policies and adjustments:

- HCPCS codes GCG0X and GPC1X, for visit complexity inherent to E/M services associated with primary care and non-procedural specialty care (e.g., endocrinology, rheumatology, etc.), respectively. [21]
- HCPCS code GPRO1, for extended time for E/M services, when the visit requires direct patient contact of 34-69 face-to-face minutes overall for existing patients or 38-89 face-to-face minutes overall for new patients. [22]

These payment adjustments will also become effective January 1, 2021. [23]

TEACHING PHYSICIAN DOCUMENTATION REQUIREMENTS FOR EVALUATION AND MANAGEMENT SERVICES

CMS finalized changes to the documentation required for payment for teaching physician services under the PFS.

[24] Currently, a teaching physician's participation in the review and direction of E/M services performed by a resident must be personally documented by the teaching physician. In an effort to reduce burden and duplication of effort for teaching physicians, [25] CMS finalized changes such that the participation of the teaching physician during E/M services need not be separately documented by the teaching physician, but may be demonstrated by the notes in the medical records made by a physician, resident, or nurse. [26] This documentation requirement will become effective January 1, 2019. [27]

THERAPY SERVICES

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% 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. [28] To implement this provision, CMS proposed to establish two new modifiers to identify separate physical therapy and occupational therapy services that are furnished in whole or in part by a therapy assistant. [29] Rather than establishing these modifiers as new therapy modifiers, as proposed, CMS opted to establish the two new modifiers as payment modifiers to be used in conjunction with existing therapy modifiers in order to reduce the administrative burden on physical therapy and occupational therapy professionals associated with the addition of new therapy modifiers. [30] In the PFS Final Rule, CMS also changed its proposed definition of a service that is furnished in whole or in part by a therapy assistant to create a de minimis standard under which a service is furnished in whole or in part by a therapy assistant when more than 10% of the service is furnished by a therapy assistant. [31]

In addition, CMS 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. [32] In response to the comments, CMS finalized its proposal to discontinue the functional reporting requirements for outpatient therapy services furnished on or after January 1, 2019. [33]

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

CMS finalized its proposal to use a 3% add-on in place of the current 6% 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. In so doing, CMS indicated that the change would reduce the financial incentive under the current system to over utilize new drugs and would not significantly affect providers through reduced margins for Part B drugs. [34]

POTENTIAL MODEL FOR RADIATION THERAPY

The Patient Access and Medicare Protection Act, [35] enacted December 28, 2015 (PAMPA), required CMS, in 2017 and 2018, to apply the same code definitions and work RVUs for the fee schedule established under Section 1848(b) of the Act and Section 1848(c)(2)(C)(ii) of the Act, and to apply the same direct inputs for the PE RVUs for radiation treatment delivery and related imaging services under Section 1848(c)(2)(C)(ii) of the Act as those definitions, units, and inputs for such services for the fee schedule established for services furnished in

2016. PAMPA also required the Secretary of Health and Human Services (HHS) to submit a report to Congress on the development of an episodic advanced payment model for Medicare payment for radiation therapy services furnished in non-facility settings. HHS delivered this report to Congress in November 2017. CMS noted that "episode payment models can be a tool for improving care and reducing expenditures" and further indicated that CMS believes that "radiation oncology is a promising area of health care for bundled payments." The PFS Final Rule states that the CMS Innovation Center will continue to use stakeholder feedback and public information regarding commercial initiatives to help inform the development, implementation, and refinement of design and testing of a potential model that tests payment for radiation therapy services. [36]

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. [37] 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 furnished by each of its components that meets the definition of an "applicable laboratory" every three years. [38] 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. [39]

As currently defined, the term "applicable laboratory" means an entity that is a laboratory, as defined in 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." [40] The majority of Medicare revenues threshold is met if the entity receives, under its NPI, more than 50% of its Medicare revenues through payment under the CLFS (42 C.F.R. part 414, subpart G) and/or the PFS (42 C.F.R. part 414, subpart B). [41] 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. [42]

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 finalized its proposal 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. [43] CMS maintains that this change will 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. [44]

As noted above, an applicable laboratory is currently defined, in part, as an entity that bills under its own NPI. However, many hospital outreach laboratories bill under the NPI of the hospital, rather than their own NPI. [45] Accordingly, in an effort to include a greater number of hospital outreach laboratories under the definition of an applicable laboratory, CMS finalized an approach, whereby hospital outreach laboratories will 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, which is used for hospital laboratory services provided to non-patients, rather than using all Medicare revenues reported under the NPI used on the bills. [46] In the

proposed rule, CMS expressed 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. [47] However, after receiving stakeholder commentary on the issue, CMS reasoned that this change will not impermissibly cause all hospital outreach laboratories to meet the definition of applicable laboratories because, in order to meet that definition, the $12,500.00 low expenditure threshold still must be met. [48]

Finally, as discussed in greater detail in our prior alert, in the Proposed Rule, CMS requested comments on a proposal to change the low expenditure threshold, and a proposal to use CLIA certificates to define applicable laboratories. In the Final Rule, CMS acknowledged stakeholder comments, but declined to finalize changes implementing either proposal. [49]

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

For Rural Health Centers (RHCs) and Federally Qualified Health Centers (FQHCs), CMS finalized the proposed payment methodology for the general care management services HCPCS code G0511, as the average of the national non-facility PFS payment rate for certain CPT codes. CMS also finalized its proposal to establish a separate payment to RHCs and FQHCs for HCPCS code G0071 (Virtual Communication Services), which represents at least five minutes of communication technology-based services or 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. [50]

APPROPRIATE USE CRITERIA FOR ADVANCED DIAGNOSTIC IMAGING SERVICES

CMS finalized many of its proposals regarding appropriate use criteria (AUC) for advanced diagnostic imaging services as initially proposed. Originally established in the CY 2016 final rule, practitioners will be required to consult evidence-based AUC when ordering and furnishing applicable imaging services to make the most appropriate treatment decisions for specific clinical conditions beginning in 2020. These proposals seek to provide additional clarification to AUC requirements that, while currently voluntary, will be required for providers effective January 1, 2020. The PFS Final Rule clarifies the following:

- independent diagnostic testing facilities are applicable settings which require AUC consultation and reporting, as initially proposed; [51]
- when not personally performed by the ordering professional, AUC consultation may be delegated to and performed by clinical staff working under the direction of the ordering professional, as modified from the initial proposal that “auxiliary personnel” may perform the AUC consultation “incident to” the ordering professional's services; [52]

- AUC consultation must be reported on all claims for applicable imaging services, including both the professional and facility claims, as initially proposed; [53]
- providers may report AUC information on claims using established coding methods, including certain G-codes and modifiers, as initially proposed; however, CMS acknowledged potential technical issues regarding this approach and stated that it will continue to address such issues during implementation; [54] and
- changes to the significant hardship exception that include insufficient internet access, electronic health record (EHR) or clinical decision support mechanism vendor issues, or extreme and uncontrollable circumstances, as initially proposed. [55]

Finally, CMS stated its intention to address outlier identification and prior authorization more fully in future CY 2022 or 2023 rulemaking. [56]

MEDICAID PROMOTING INTEROPERABILITY PROGRAM REQUIREMENTS FOR ELIGIBLE PROFESSIONALS

CMS finalized without change its proposal to amend the list of available eCQMs for the CY 2019 performance period. [57] Through these changes, CMS aligns 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 that the eCQMs available for Medicaid EPs in 2019 consist of the quality measures available under the eCQM collection type on the final list of quality measures established under MIPS for the CY 2019 performance period. [58]

CMS also finalized its proposal for CY 2019 that requires Medicaid EPs to report on any six eCQMs that are relevant to the EP's scope of practice, either via attestation or electronically. [59] Additionally, CMS finalized its proposal 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). [60] CMS explains in the PFS Final Rule that, if no outcome or high-priority measure is relevant to a Medicaid EP's scope of practice, the EP may report on any six eCQMs relevant to his or her practice. [61]

Furthermore, CMS finalized its proposal to allow states to indicate which eCQMs are high-priority measures for that state's Medicaid agency. [62] CMS reiterates that, if no outcome or priority measure is relevant to the Medicaid EP's scope of practice, he or she may report on six relevant measures. [63]

CMS finalized its proposal that the eCQM reporting period for EPs in the Medicaid Promoting Interoperability Program will be a full CY in 2019 for EPs that have demonstrated meaningful use in a prior year, in order to align with the corresponding performance period in MIPS for the quality performance category. [64] CMS also finalized the EHR reporting period in 2021 for all EPs in the Medicaid Promoting Interoperability Program as a minimum of any continuous 90-day period within CY 2021, provided that the end date for this period falls before October 31, 2021. [65]

Finally, 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), CMS finalized its change to the thresholds so that they will remain at 5% for 2019 and subsequent years. [66]

PHYSICIAN SELF-REFERRAL LAW & ANNUAL UPDATE TO THE LIST OF CPT/HCPCS CODES

In order to align the Stark Law regulations with Stark Law statutory amendments enacted as part of the Bipartisan Budget Act of 2018, CMS had proposed amendments to existing requirements for a written agreement and signature requirements.

- **Written Agreement:** CMS proposed 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. CMS received a few comments in support of its proposal to codify its existing policy on the writing requirement, and received no comments opposing its proposal. CMS finalized the proposed § 411.354(e) without modification. [67]
- **Signature Requirements:** CMS also proposed modifications to the regulatory provision 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. In the alternative, CMS proposed deleting the regulatory section 42 C.F.R. § 411.353(g) in its entirety, which set out the special rules for arrangements involving temporary noncompliance with the signature requirement, and instead codifying the statutory language setting forth the special rule for signature requirements. CMS received a few comments expressing general support for the special rule on temporary noncompliance with signature requirements, and no comments opposing the proposal. [68] CMS noted that it will be less disruptive to amend the existing regulation at § 411.353(g), rather than delete the section in its entirety and codify the statutory language in a new regulatory section. [69]

  As such, CMS finalized its proposal to revise the special rule for temporary noncompliance with signature requirements at § 411.353(g), thus aligning § 411.353(g) with the newly added statutory provision. Finally, CMS notes that the effective date of the applicable Bipartisan Budget Act section was February 9, 2018, and as such, beginning on that date, parties who met the requirements of the statutory provision regarding noncompliance with signature requirements, but otherwise would have been barred from relying on the special rule for certain arrangements involving temporary noncompliance with signature requirements because of the three-year limitation, may avail themselves of the new statutory provision of that date. [70]
- **Annual Update to the Code List:** CMS also published the annual list of the additions and deletions to the comprehensive list of CPT codes considered DHS for purposes of four categories of DHS: (1) clinical laboratory services; (2) physical therapy, occupational therapy, and outpatient speech-language pathology services; (3) radiology and certain other imaging services; and (4) radiation therapy services and supplies. The updated Code List becomes effective January 1, 2019. [71]

CY 2019 UPDATES TO THE QUALITY PAYMENT PROGRAM

The PFS Final Rule makes a significant number of operational changes to the Quality Payment Program (QPP), as QPP enters its third transitional year. These changes cover a wide variety of issues impacting both the Merit-Based Incentive Payment System (MIPS) and the Advanced Alternative Payment Model program (Advanced APM). The majority of the updates introduced in the Proposed Rule were finalized without change.

A future client alert will discuss these QPP changes in-depth. However, some key finalized provisions include the following:

- expanding the definition of a "MIPS eligible clinician" to add a number of additional clinician-types, such as physical and occupational therapists; [72]
- revising the MIPS final score performance category weights; [73]
- altering the methodology for calculating the small practice performance bonus under MIPS; [74]
- several modifications to the recently introduced facility-based measurement option under MIPS, including adding on-campus outpatient hospitals (POS-code 22) to the list of site of services that CMS will use to determine eligibility for facility-based measurement; [75]
- 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. [76] In addition, CMS is setting the "additional performance threshold" (the point at which a clinician is eligible for sharing in $500,000,000 of additional incentive funding) at 75 points for MIPS payment year 2021, slightly less than the 80 points initially proposed; [77] and
- increasing the certified EHR technology (CEHRT) threshold for an APM to qualify as an Advanced APM, by requiring at least 75% of eligible clinicians participating in an Advanced APM to use CEHRT starting in calendar year 2019, up from the current threshold of 50%. [78]

MEDICARE SHARED SAVINGS PROGRAM; ACCOUNTABLE CARE ORGANIZATIONS—PATHWAYS TO SUCCESS

The PFS Final Rule also contains several provisions related to updating Medicare Shared Savings Program (MSSP) rules. [79] These changes include finalizing proposals introduced in the PFS Proposed Rule, as well as finalizing some of the proposals introduced in the recent "Pathway to Success" proposed rule related to MSSP. A number of the proposed changes from the Pathway to Success proposed rule are not addressed in the PFS Final Rule, however, and will be addressed in future rulemaking, including the proposed restructuring of MSSP program design. A summary of the MSSP changes contained in the PFS Final Rule will be the subject of a future client alert.

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 finalized its proposal to amend § 410.32(b) such that any diagnostic tests that would otherwise require personal supervision will now only require direct supervision when performed by a registered radiologist assistant (RRA) 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. [81] Diagnostic imaging tests requiring a general level of physician supervision still only require general supervision. [82]

CONCLUSION

As underscored in this alert, the changes implemented in the PFS Final Rule are significant and wide ranging in their scope.

Providers will need to quickly assess both the practical compliance elements of implementing the changes identified in the PFS Final Rule and the financial impact of those changes on their budgets. K&L Gates' Health Care Practice can assist health care providers in conducting this analysis and will continue to closely monitor further developments as these changes are applied and further subregulatory guidance is issued.

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; Medicaid Promoting Interoperability Program; Quality Payment Program--Extreme and Uncontrollable Circumstance Policy for the 2019 MIPS Payment Year; Provisions from the Medicare Shared Savings Program--Accountable Care Organizations--Pathways to Success; and Expanding the Use of Telehealth Services for the Treatment of Opioid Use Disorder under the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act, *available at* https://federalregister.gov/d/2018-24170 (unpublished November 1, 2018).
[2] *Id.* at 104–56.
[3] Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act, Pub. L. 15-271, __ Stat. __ (October 24, 2018).
[4] PFS Final Rule at 156–58.
[5] *Id.* at 158–63.
[6] *Id.* at 197.
[7] *Id.* at 213.
[8] *Id.* at 208.
[9] *Id.* at 537.
[10] *Id.* at 539.
[11] *Id.* at 537.
[12] *Id.* at 536.
[13] *Id.* at 565.

[14] *Id.* at 565–66. Regarding time, CMS notes that "[f]or administrative simplicity, it may be most straight forward to track to the typical time for the CPT code." *Id.* at 566. 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.
[15] 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).
[16] 83 Fed. Reg. 35,839.
[17] PFS Final Rule at 578.
[18] *Id.* at 581.
[19] *Id.*
[20] *Id.*
[21] *Id.* at 606.
[22] *Id.* at 620.
[23] *Id.*
[24] *Id.* at 633.
[25] *Id.*
[26] *Id.* at 634.
[27] *Id.* at 635.
[28] *Id.* at 640.
[29] *Id.* at 650.
[30] *Id.* at 651.
[31] *Id.* at 660.
[32] *Id.* at 664.
[33] *Id.*
[34] *Id.* at 677.
[35] Pub. L. 114–15, 129 Stat. 3131 (December 28, 2015).
[36] PFS Final Rule at 686.
[37] *Id.* at 687–88.
[38] *Id.* at 689.
[39] *Id.* at 688.
[40] *Id.*
[41] *Id.* at 691.
[42] *Id.* at 688.
[43] *Id.* at 701.
[44] *Id.*
[45] *Id.* at 706-07.
[46] *Id.* at 718.
[47] *Id.* at 710.
[48] *Id.* at 719.
[49] *Id.* at 723–25, 729, 732.
[50] *Id.* at 746–65.

[51] *Id.* at 777.
[52] *Id.* at 785-86.
[53] *Id.* at 788–89.
[54] *Id.* at 798.
[55] *Id.* at 812.
[56] *Id.*
[57] *Id.* at 815, 821.
[58] *Id.* at 821–22.
[59] *Id.* at 824.
[60] *Id.*
[61] *Id.*
[62] *Id.* at 825.
[63] *Id.*
[64] *Id.* at 826–27.
[65] *Id.* at 830.
[66] *Id.* at 832, 839.
[67] *Id.* at 862–63.
[68] *Id.* at 863–64.
[69] *Id.* at 865.
[70] *Id.* at 866.
[71] *Id.* at 867-69.
[72] *Id.* at 906.
[73] *Id.* at 1003.
[74] *Id.* at 1305–06.
[75] *Id.* at 1338.
[76] *Id.* at 1419.
[77] *Id.* at 1428.
[78] *Id.* at 1550.
[79] *Id.* at 837–63, 1621–1805.
[80] http://healthcare-triage.klgates-media.libsynpro.com/category/Accountable+Care+Organizations+%28ACO%29%2C+Clinically+Integrated+Networks+%28CIN%29+%26amp%3B+Bundled+Payments
[81] PFS Final Rule at 190.
[82] *Id.* at 188.

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