On July 13, 2021 the Calendar Year 2022 Medicare Physician Fee Schedule and Quality Payment Program proposed rule was released. The rule proposes changes to Medicare payment policies for 2021. Comments are due September 13, 2021. Below is a summary of health IT-related proposed changes.

Medicare Physician Fee Schedule	
Issue Area	**CMS Proposal**

Telehealth Services	• None of the requests to add telehealth services met CMS' Category 1 or 2 criteria for permanent addition to the Medicare telehealth services list
	• Propose to retain all services added to the Medicare telehealth services list on a Category 3 (temporary) basis until the end of CY 2023
	• Table 11 lists services added on a Category 3 basis
	• The Consolidated Appropriations Act, 2021 removed geographic and originating site restrictions for reimbursement of telemental health services
	  ○ Section 123(a) of the CAA also added subparagraph (B) to section 1834(m)(7) of the Act to prohibit payment for a telehealth service furnished in the patient's home under paragraph (7) unless the physician or practitioner furnishes an item or service in-person, without the use of telehealth, within 6 months prior to the first time the physician or practitioner furnishes a telehealth service to the beneficiary, and thereafter, at such times as the Secretary determines appropriate
	  ○ Section 123(a) of the CAA added a clarification at section 1834(m)(7)(B)(ii) of the Act that the periodic requirement for an in-person item or service does not apply if payment for the telehealth service furnished would have been allowed without the new amendments. As such, the requirement for a periodic in-person item or service applies only for telehealth services furnished for purposes of diagnosis, evaluation, or treatment of a mental health disorder other than for treatment of a diagnosed SUD or co-occurring mental health disorder, and only in locations that do not meet the geographic requirements in section 1834(m)(4)(C)(i) of the Act or when the originating site is the home of the patient, regardless of geography
	  ○ Seeking comment on whether CMS should adopt a claims-based mechanism to distinguish between the mental health telehealth services that are within the scope of the CAA amendments and those that are not and if so, what the mechanism should be
	  ○ Also seeking comment on whether or not CMS should add a clarification in the underlying regulatory text that t the physician or practitioner must furnish an item or service in person, without the use of telehealth, within a specified time frame shall not apply to telehealth services furnished for treatment of a diagnosed substance use disorder or co-occurring mental health disorder, or to services furnished in an originating site described in paragraphs (b)(3)(i) through (viii) or (xiii) that meets the geographic

	requirements specified in paragraph (b)(4) other than (b)(4)(iv)(D) ○ CMS is proposing that as a condition of payment for telemental health services (other than those that would have been paid before the CAA), the billing physician or practitioner must have furnished an in-person, non-telehealth service to the beneficiary within the 6-month period before the date of the telehealth service ○ Seeking comment on whether the required in-person, non-telehealth service could also be furnished by another physician or practitioner of the same specialty and same subspecialty within the same group as the physician or practitioner who furnishes the telehealth service ○ Proposing to require that an inperson, non-telehealth service must be furnished by the physician or practitioner at least once within 6 months before each telehealth service furnished for the diagnosis, evaluation, or treatment of mental health disorders by the same practitioner, other than for treatment of a diagnosed SUD or co-occurring mental health disorder, and that the distinction between the telehealth and non-telehealth services must be documented in the patient's medical record ○ CMS chose this interval because we are concerned that an interval less than 6 months may impose potentially burdensome travel requirements on the beneficiary, but that an interval greater than 6 months could result in the beneficiary not receiving clinically necessary in-person care/observation • During the COVID-19 public health emergency, CMS used emergency waiver authority to allow for reimbursement of audio-only E/M codes, but waiver authority ends at the end of the PHE • In the CY21 final rule, CMS noted that they continue to believe their longstanding regulatory definition of "telecommunications system" reflected the intent of statute and that the term should continue to be defined as including two way, real-time, audio/video communication technology • CMS was concerned that the use of audio-only communications technology for Medicare telehealth services could lead to inappropriate overutilization, and believed that video visualization of the patient generally was necessary to fulfill the full scope of service elements of the codes included on the Medicare telehealth list • After reviewing claims from during the COVID-19 PHE, CMS saw that audio-only E/M visits have been some of the most commonly performed telehealth services during the PHE, and that most of the beneficiaries receiving these services were receiving them for treatment of a mental health condition. Also, utilization of telehealth for mental health services has not declined over the PHE, as other services have • Given shortage of mental health professionals and barriers such as lack of high-speed, reliable broadband, CMS is proposing to amend regulation at § 410.78(a)(3) to define interactive telecommunications system to include audio-only communications technology when used for telehealth services for the diagnosis, evaluation, or treatment of mental health disorders furnished to established patients when the originating site is the patient's home • Proposing to adopt a similar ongoing requirement that an in-person item or service must be furnished within 6 months of such a mental health telehealth service • Proposing to limit payment for audio-only services to services furnished by physicians or practitioners who have the capacity to furnish two-way, audio/video telehealth services but are providing the mental health services via audio-only communication technology in an instance where the beneficiary is unable to use, does not wish to use, or does not have access to two-way, audio/video technology • In the interests of monitoring utilization and program integrity concerns for audio-only telehealth services furnished under the terms of this proposed exception, CMS is proposing to create a service-level modifier that would identify these mental health telehealth services furnished to a beneficiary in their home using audio-only communications technology • Seeking comment on what, if any, additional documentation should be required in the patient's medical record to support the clinical appropriateness of providing audio-only telehealth services for mental health in the event of an audit or claims denial

	• Seeking comment on whether, for purposes of the proposed audio-only mental health telehealth services exception, we should exclude certain higher-level services, such as level 4 or 5 E/M visit codes, when furnished alongside add-on codes for psychotherapy, or codes that describe psychotherapy with crisis
Other Non-Face-to-Face Services Involving Communications Technology under the PFS	• Proposing to permanently adopt coding and payment for CY 2022, HCPCS code G2252 as a direct crosswalk to CPT code 99442, the value of which we believe most accurately reflects the resources associated with a longer service delivered via synchronous communication technology, which can include audio-only communication
Comment request on resource costs for services involving the use of innovative technologies	• CMS is soliciting public comment to help better understand the resource costs for services involving the use of innovative technologies, including but not limited to software algorithms and AI • To what extent are services involving innovative technologies such as software algorithms and/or AI substitutes and/or supplements for physician work? To what extent do these services involving innovative technology inform, augment, or replace physician work? For example, CPT code 92229 is a PE-only code in which the software algorithm may be substituting for some work of an ophthalmologist to diagnose/detect diabetic retinopathy. CPT code 77X01 is a service in which the trabecular bone score software may be supplementing physician work to predict and detect fracture risk. CPT code 0503T may be both substituting for, and supplementing physician work to detect coronary artery disease • How has innovative technology such as software algorithms and/or AI affected physician work time and intensity of furnishing services involving the use of such technology to Medicare beneficiaries? For example, if a new software algorithm or AI technology for a diagnostic test results in a reduction in the amount of time that a practitioner spends reviewing and interpreting the results of a diagnostic test that previously did not involve such software algorithm or AI technology, and if the software algorithm or AI could be considered in part a substitute for at least some physician work, it may follow that the intensity of the service decreases. It is also possible that a software algorithm for a diagnostic test that is supplementing other tests to establish a diagnosis or treatment pathway for a particular condition could result in an increase in the amount of time that a practitioner spends explaining the test to a patient and then reviewing the results. • How is innovative technology such as software algorithms and/or AI changing cost structures in the physician office setting? As discussed previously, the PPIS data that underlie the PE methodology were last collected in 2007 and 2008, which was prior to the widespread adoption of electronic health records and services that involve care management, non-face-to-face and/or asynchronous remote care; the need to use electronic clinical quality measure data to support quality improvement, disparity identification and resolution, and value based payment; and the emergence of software algorithms and/or AI and other technologies that use data to inform, augment, or replace physician work in the delivery of health care. Do costs for innovative technology such as software algorithms and/or AI to furnish services to patients involve a one-time investment and/or recurring costs? How should CMS consider costs for software algorithms and/or AI that use patient data that were previously collected as part of another service? As technology adoption grows, do these costs decrease over time? • How is innovative technology affecting beneficiary access to Medicare-covered services? How are services involving software algorithms and/or AI being furnished to Medicare beneficiaries and what is important for CMS to understand as it considers how to accurately pay for services involving software algorithms and/or AI? For example, it is possible that services that involve software algorithms and/or AI may allow a practitioner to more efficiently furnish care to more Medicare beneficiaries, potentially increasing access to care. Additionally, to what extent have services that involve innovative technology such as software algorithms and/or AI affected access to Medicare-covered services in rural and/or underserved areas, or for beneficiaries

	that may face barriers (homelessness, lack of access to transportation, lower levels of health literacy, lower rates of internet access, mental illness, having a high number of chronic conditions/frailty, etc.) in obtaining health care? • Compared to other services paid under the PFS, are services that are driven by or supported by innovative technology such as software algorithms and/or AI at greater risk of overutilization or more subject to fraud, waste, and abuse? As CMS is considering appropriate payment for services enabled by new technologies, there are considerations for program integrity. For example, section 218(b) of the PAMA required that we establish an Appropriate Use Criteria Program to promote appropriate use of advanced diagnostic imaging services provided to Medicare beneficiaries1 . To what extent do services involving innovative technology require mechanisms such as appropriate use criteria to guard against overutilization, fraud, waste, or abuse? • Compared to other services paid under the PFS, are services driven by or supported by innovative technology such as software algorithms and/or AI associated with improvements in the quality of care or improvements in health equity? For example, increased access to services to detect diabetic retinopathy such as the service described by CPT code 92229 could eventually lead to fewer beneficiaries losing their vision. Because CPT code 92229 can be furnished in a primary care practice's office and may not require the specialized services of an ophthalmologist, more beneficiaries could have access to a test, including those who live in areas with fewer ophthalmologists. Additionally, taking into consideration that a software algorithm and/or AI may introduce bias into clinical decision making that could influence outcomes for racial and ethnic minorities and people who are socioeconomically disadvantaged, are there guardrails, such as removing the source of bias in a software algorithm and/or AI, that Medicare should require as part of considering payment amounts for services enabled by software algorithm and/or AI? • CMS' proposals to use crosswalks to set values for codes describing diabetic retinopathy and trabecular bone score would allow us to account for overall resource costs involved in furnishing the services. The possible crosswalks for FFRCT may also account for overall resource costs involved in furnishing the service. CMS also believes it is important to accurately account for resource costs for innovative and emerging technologies such as ongoing service-specific software costs and, as explained above, such costs are not well accounted for in the PE methodology. CMS continues to be interested in potentially refining the PE methodology and updating the underlying data, including the PPIS data that are the data source that underpins the Appropriate Use Criteria Program (https://www.cms.gov/Medicare/Quality-Initiatives-Patient-AssessmentInstruments/Appropriate-Use-Criteria-Program) indirect PE allocation. How might CMS consider updating such data to reflect ongoing advances in technology so that we could establish appropriate relative values without resorting to crosswalks? The RAND Corporation laid out a number of issues for CMS to consider in two reports - https://www.rand.org/pubs/research_reports/RR2166.html, and RAND's second phase of research, available at https://www.rand.org/pubs/research_reports/RR3248.html.
Remote Therapeutic Monitoring	• Remote Therapeutic Monitoring (RTM) is a family of five codes (CPT codes 989X1, 989X2, 989X3, 989X4, and 989X5) created by the CPT Editorial Panel in October 2020 and valued by the RUC at its January 2021 meeting • Two main differences between RTM and RPM codes: who is supposed to be able to bill for the codes and the data collected/how it is collected • According to RUC documents, primary billers of RTM codes are projected to be nurses and physical therapists; however, because the RTM codes are modeled after the RPM codes, "incident to" services became a part of the RTM codes. As a result, due to the way RTM codes are currently constructed, they cannot be billed by those practitioners • Additionally, because RTM codes are E/M codes, they cannot be designated as care management services • CMS is seeking comment on how they might remedy the issues related to the RTM code construction in order

	to permit practitioners who are not physicians or NPPs to bill the RTM codes • The second primary difference between the RTM and RPM codes is the nature of the data to be collected and how it is collected - According to the code descriptors, RTM codes monitor health conditions, including musculoskeletal system status, respiratory system status, therapy (medication) adherence, and therapy (medication) response, and as such, allow non-physiologic data to be collected • Reportedly, data also can be self-reported as well as digitally uploaded. RPM requires that data be physiologic and be digitally uploaded • For both sets of codes, the device used must meet the FDA definition of a medical device as described in section 201(h) of the Federal Food, Drug and Cosmetic Act (FFDCA) • Seeking comment on the typical type of device(s) and associated costs of the device(s) that might be used to collect the various kinds of data included in the code descriptors (for example, respiratory system status, musculoskeletal status, medication adherence, pain) for the RTM services • For CY 2022, CMS is proposing the RUC-recommended work RVU of 0.62 for CPT code 989X4 (Remote therapeutic monitoring treatment management services, physician/ other qualified health care professional time in a calendar month requiring at least one interactive communication with the patient/caregiver during the calendar month; first 20 minutes) and the RUC-recommended work RVU of 0.61 for its add-on code, CPT code 989X5 (Remote therapeutic monitoring treatment management services, physician/other qualified health care professional time in a calendar month requiring at least one interactive communication with the patient/caregiver during the calendar month; each additional 20 minutes (List separately in addition to code for primary procedure)) as a means of maintaining parity with the two RPM treatment management codes (CPT codes 99457 and 99458) upon which the two RTM codes are based • Also proposing the RUC-recommended direct PE inputs for the two treatment management codes, CPT codes 989X4 and 989X5, without refinement • CMS is proposing to value the PE for CPT code 989X1 by crosswalking to the PE RVU for RPM code 99453 upon which the new RTM code was based • Also proposing to value the PE for CPT codes 989X2 and 989X3 by crosswalking to the PE RVU for comparable RPM code 99454, a code that includes payment for the medical device used to collect and transmit data
Direct Supervision by Interactive Telecommunications Technology (Ref. pg 114)	• Through the March 31st COVID-19 IFC, CMS changed the definition of “direct supervision” during the PHE for COVID-19 (85 FR 19245 through 19246) as it pertains to supervision of diagnostic tests, physicians’ services, and some hospital outpatient services, to allow the supervising professional to be immediately available through virtual presence using real-time audio/video technology, instead of requiring their physical presence. • CMS is continuing to seek information on whether this flexibility should be continued beyond the later of the end of the PHE for COVID-19 or CY 2021. ○ Specifically, CMS is seeking comment on the extent to which the flexibility to meet the immediate availability requirement for direct supervision through the use of real-time, audio/video technology is being used during the PHE, and whether physicians and practitioners anticipate relying on this flexibility after the end of the PHE. ○ CMS is seeking comment on whether this flexibility should potentially be made permanent, meaning that they would revise the definition of “direct supervision” at § 410.32(b)(3)(ii) to include immediate availability through the virtual presence of the supervising physician or practitioner using real-time, interactive audio/video communications technology without limitation after the PHE for COVID-19, or if they should continue the policy in place for a short additional time to facilitate a gradual sunset of the policy. ○ CMS is soliciting comment on whether the current timeframe for continuing this flexibility at §

	410.32(b)(3)(ii), which is currently the later of the end of the year in which the PHE for COVID-19 ends or December 31, 2021, remains appropriate, or if this timeframe should be extended through some later date to facilitate the gathering of additional information in recognition that, due to the on-going nature of the PHE for COVID-19, practitioners may not yet have had time to assess the implications of a permanent change in this policy. ○ CMS seeks comment regarding the possibility of permanently allowing immediate availability for direct supervision through virtual presence using real-time audio/video technology for only a subset of services, as they recognize that it may be inappropriate to allow direct supervision without physical presence for some services, due to potential concerns over patient safety if the practitioner is not immediately available in-person. ○ CMS is seeking comment on, were this policy to be made permanent, if a service level modifier should be required to identify when the requirements for direct supervision were met using two-way, audio/video communications technology.
Medicare Diabetes Prevention Program (MDPP)	• CMS proposes to preclude the provision of ongoing maintenance sessions unless the MDPP beneficiary has started his or her first core session on or before December 31, 2021 • CMS proposes to update the amount of the performance payment for the core session and core maintenance sessions and ongoing maintenance sessions (where applicable) to be consistent with the proposal herein • CMS proposes that this change apply to all MDPP beneficiaries starting the MDPP set of services on or after January 1, 2022 • CMS proposes to add a provision to waive the provider enrollment Medicare application fee for all organizations enrolling in Medicare as MDPP suppliers that submit an application on or after January 1, 2022 • CMS is proposing to redistribute a portion of the ongoing maintenance sessions phase performance payments to certain core and core maintenance session performance payments to address stakeholder concerns that the current MDPP payment structure does not cover reasonable costs of MDPP suppliers to deliver the MDPP set of services • CMS is proposing a change to their emergency policy at § 410.79(e)(3)(v)(C) to account for the proposed elimination of ongoing maintenance sessions for MDPP beneficiaries who start the set of MDPP services on or after January 1, 2022 ○ Under this proposal, only beneficiaries who start the MDPP set of services between January 1, 2021, and December 31, 2021 and who are in the second year of the set of MDPP services as of the start of an applicable 1135 waiver event may either resume or restart the ongoing maintenance session interval in which they were participating at the start of the applicable 1135 waiver event if they elect not to continue with MDPP services virtually during the applicable 1135 waiver event • CMS proposes removing the ongoing maintenance sessions phase for all MDPP beneficiaries who start MDPP set of services on or after January 1, 2022 • Table 29 summarizes proposals for the MDPP services period based on beneficiary start date
Requirement for Electronic Prescribing for Controlled Substances for a Covered Part D Drug under a Prescription Drug Plan or an MA-PD Plan	• CMS is proposing to change the EPCS compliance date from January 1, 2022 to January 1, 2023 ○ CMS welcomes comments on this proposal, including whether commenters believe that they should maintain the January 1, 2022 compliance date, given the benefits of EPCS, and the feasibility for prescribers to adopt EPCS for Part D prescriptions by January 1, 2023 • CMS proposes to extend the compliance deadline for Part D controlled substance prescriptions written for beneficiaries in long-term care (LTC) facilities, excluding beneficiaries who are residents of nursing facilities and whose care is provided under Part A of the benefit, from January 1, 2022 to January 1, 2025

	• CMS notes that the section 1860D-4(e)(7)(B)(vi) of the Act provides that the Secretary may grant an exception for a prescription issued for a drug for which the FDA requires a prescription to contain elements that cannot be included in electronic prescribing. However, after reviewing the NCPDP standard implementation guide, CMS does not believe that there are any such prescriptions under the current standard. o They are requesting comments on this decision. • CMS proposes that in order for prescribers to be considered compliant with the EPCS mandate, they must prescribe at least 70 percent of their Part D controlled substance prescriptions electronically • CMS is proposing to specify that 70 percent of all prescribing under Part D for Schedule II, III, IV, and V controlled substances be done electronically per calendar year, excluding from that calculation any prescriptions issued while a prescriber falls within an exception or a waiver • CMS will conduct this calculation by examining PDE data at the end of the calendar year and dividing the number of Part D controlled substances that the prescriber e-prescribed by the total number of Part D controlled substance prescriptions that the prescriber prescribed o CMS is requesting comment on this method and the proposal to make 70 percent the compliance threshold for adherence to the EPCS mandate, and what circumstances would make EPCS not feasible • CMS currently allows Part D plans to use either HL7 messages or the NCPDP SCRIPT standard to transmit prescriptions or prescription-related information internally when the sender and the beneficiary are part of the same legal entity • After reviewing the current PDE data and the costs associated with implementing EPCS, CMS proposes to exempt prescribers who prescribe 100 or fewer Part D controlled substance prescriptions per year • Based on CMS conversations with stakeholders, the cost of EPCS transactions is less than the cost of transmitting certain transactions manually, CMS believes that the initial investment to install EPCS equipment and software is likely justified once prescribers transmit more than 100 Part D controlled substance prescriptions per year. Seek comment on this assumption • Although CMS understands that prescribers will be required to purchase third party applications with additional identity and security measures so that EHRs meet DEA requirements, they have not included this cost in their calculation, due to the wide variability of these costs for which there is a dearth of information o CMS seeks stakeholder feedback on the costs of these third-party applications • Although CMS considered using a lower threshold (such as 50) or a higher threshold (such as 200), they believe that 100 Part D controlled substance prescriptions per year strikes the right balance between helping ensure that they implement section 2003 of the SUPPORT Act's EPCS mandate and that prescribers can use resources appropriately o CMS is proposing that this exception be given to individual prescribers, regardless of the size of the group practice that they belong to • CMS also believes that this exception would protect these small prescribers, should they change their place of employment or if their place of employment does not offer support for implementing EPCS o CMS seeks comment on this proposal • CMS believes an exception for prescribers working under a research protocol who do not otherwise meet these exceptions is unnecessary because they believe that EHR companies will set up the appropriate EHR equipment, provided around 100 Part D controlled substance prescriptions are transmitted per year o They propose to implement this proposal by examining PDE claims as of December 31 of the prior year to determine which prescribers fall within this exception • Based on the conversations with Prescription Drug Plans (PDPs), MA-PD plans, and other organizations with which prescribers are affiliated, they are aware that some are willing to donate the technology and services necessary for prescribers to adopt EPCS. Based on those conversations, they believe that they are more willing to donate these technology and services to prescribers who are working under a research protocol, than to

prescribers not working under such a protocol. They are seeking comment on this assumption

- CMS believes that, to the extent this is an accurate assumption, such donations further decrease the burden for prescribers working under a research protocol. It is for these additional reasons that they have declined to propose an exception for those working under a research protocol. They seek comment on this decision.
- After these conversations, CMS believe that they are more willing to donate these technology and services to prescribers who are working under a research protocol, than to prescribers not working under such a protocol. They seek comment on such an assumption.
- CMS believes that, to the extent this is an accurate assumption, such donations further decrease the burden for prescribers working under a research protocol.
    - It is for these reasons that CMS has declined to propose an exception for those working under a research protocol.
    - They seek comment on this decision.
- CMS believes that the exception listed in the statute, which includes economic hardship, technological limitations that are not reasonably within the control of the prescriber, and other exceptional circumstances, includes prescribers who are overwhelmed due to having to treat patients during a pandemic or a natural disaster such as a hurricane, flood, or earthquake.
    - It is their goal not to penalize prescribers for such circumstances, and they do not want to unduly increase their burden during difficult situations that impact them, and their patients.
    - CMS seeks comment on what other extraordinary circumstances may prevent prescribers from being able to conduct
- In order to help ensure that these extraordinary circumstances are accounted for, CMS is proposing two exceptions to the EPCS requirement.
    - The first exception is for prescribers who are prescribing during a recognized emergency, such as a natural disaster, a pandemic, or a similar situation where there is an environmental hazard
        - CMS wants to help ensure that the EPCS mandate does not interfere with necessary care for patients, especially during natural disasters or pandemics
        - As a result, CMS is proposing to exempt prescribers who are issuing prescriptions in areas that are affected by such circumstances
    - The second exception is for prescribers who request and receive from CMS a waiver, which CMS would grant to prescribers who are facing extraordinary circumstances that prevent them from electronically prescribing a controlled substance to a Part D beneficiary, but who are not in an emergency or disaster area
- For purposes of the proposed exception, CMS is proposing that prescribers will be excepted from the EPCS requirements if they request and receive a waiver from CMS
- Under the proposed policy, the prescriber would submit their attestation about the circumstance and receive a waiver based on such an attestation
    - CMS welcomes comments on the different aspects of this proposal
- CMS declines to propose an exemption for prescribers issuing prescriptions for individuals enrolled in hospice
    - CMS seeks comment on this decision
- CMS declines to propose an exemption for prescribers issuing prescriptions for individuals who are residents of a nursing facility and eligible for Medicare and Medicaid benefits
    - CMS seeks comment on this issue
- CMS proposes that with respect to compliance from January 1, 2023 through December 31, 2023, CMS compliance actions will consist of sending letters to prescribers that we believe are violating the EPCS requirement during that period of time
    - CMS seeks comment on this proposal, including what type of compliance action may be appropriate after

	the initial period described above, including whether any penalties should be phased in over time.
Quality Payment Program	
Issue Area	**CMS Proposal**
Promoting Interoperability Performance Category - MVPs	• Propose to use the scoring methodology established for the Promoting Interoperability performance category in traditional MIPS and for MVP Participants, except for subgroups who would be scored based on their affiliated group's Promoting Interoperability performance category data
Promoting Interoperability Performance Category	• For the 2024 MIPS payment year, the performance period for the Promoting Interoperability performance category is a minimum of any continuous 90-day period within CY 2022, up to and including the full CY 2022 (January 1, 2022 through December 31, 2022) • CMS believes that at least 1 more year is needed prior to potentially requiring the Query of PDMP measure - proposing to maintain the Electronic Prescribing Objective's Query of PDMP measure as optional and worth 10 bonus points for the CY 2022 performance period/2024 MIPS payment year o CMS believes there is a concrete path forward on the measure given the work on the RxCheck Hub o This solution will enable health care providers to query PDMPs via existing connections to health information exchange (HIE) networks as a way to: (1) leverage existing technology; (2) reduce burden associated with multiple, disparate system interfaces and workflows; and (3) allow for the exchange and full integration of data within allowable law from the point of exchange for medication reconciliation, allergy checks, and other forms of clinical decision support o CMS requests feedback on future direction of the measure: ▪ To what degree would all MIPS eligible clinicians be prepared to report on the current Query of PDMP measure (Yes/No response) in the near future? What additional considerations would need to be addressed before transitioning to a version of the measure that requires the submission of a numerator/denominator? ▪ Would changes to the Query of PDMP measure be necessary to accommodate other technical approaches that may be implemented in the future, such as exchange of information with a PDMP or with multiple PDMPs using HL7® FHIR®? ▪ What, if any, exclusions should be made available as part of the measure's specifications with regard to MIPS eligible clinicians? ▪ When will state PDMPs be ready to effectively exchange data with provider systems using HL7® FHIR® to support this measure? What are the most common standards and approaches used to access PDMP data through provider systems currently? ▪ What technical considerations exist for intrastate vs. interstate PDMP queries? How could health information exchange networks play a role in expanding access to PDMP data? In what ways could FHIR® applications be supported to safely share PDMP data within a clinician's workflow? • Proposing to modify the Provide Patients Electronic Access to Their Health Information measure to require MIPS eligible clinicians to ensure that patient health information remains available to the patient (or patient-authorized representative) to access indefinitely and using any application of their choice that is configured to meet the technical specifications of the API in the MIPS eligible clinician's CEHRT o The proposed requirement would apply beginning with the performance period in 2022, and would include all patient health information from encounters on or after January 1, 2016

	• Proposing to require two of the measures associated with the Public Health and Clinical Data Exchange Objective, beginning with the performance period in CY 2022: Immunization Registry Reporting; and Electronic Case Reporting
	• Proposing to make the Immunization Registry Reporting a required measure under the Public Health and Clinical Data Exchange objective of the Promoting Interoperability performance category beginning with the performance period in CY 2022 as it is critical for understanding vaccination coverage both at the jurisdiction level and nationwide and identifying where additional vaccination efforts are needed
	• Proposing to make the Electronic Case Reporting measure a required measure under the Public Health and Clinical Data Exchange objective of the Promoting Interoperability performance category beginning with the performance period in CY 2022
	• Proposing that beginning with the performance period in CY 2022, a MIPS eligible clinician would receive 10 points for the Public Health and Clinical Data Exchange objective if they report a "yes" response for each of the following required measures: Immunization Registry Reporting; and Electronic Case Reporting
	• Proposing to retain the Public Health Registry Reporting, Clinical Data Registry Reporting, and Syndromic Surveillance Reporting measures, and to make them optional and available for bonus points beginning with the performance period in CY 2022
	• Proposing to remove the three exclusions that we established in the CY 2019 PFS final rule at 83 FR 59815 through 59817 for the Public Health Registry Reporting measure, Clinical Data Registry Reporting measure, and the Syndromic Surveillance Reporting measure
	• Proposing to add a new SAFER Guides measure to the Protect Patient Health Information objective, beginning with the CY 2022 performance period/2024 MIPS payment year
	  ○ Proposing that a MIPS eligible clinician must attest to having conducted an annual self-assessment using the High Priority Practices Guide at any point during the calendar year in which the performance period occurs, with one "yes/no" attestation statement accounting for the complete self-assessment using the guide
	  ○ Propose that this measure would be required, but it would not be scored, and that reporting "yes" or "no" would not affect the total number of points earned for the Promoting Interoperability performance category
	• Table 44 lists the objectives and measures for the Promoting Interoperability Performance Category in 2022
	• Table 45 lists the objectives and measures and 2015 Edition CEHRT requirement
	• Table 46 lists the scoring methodology
	• Proposing to no longer require statements B and C as a part of their information blocking attestation. B & C are:
	  ○ Statement B: Implemented technologies, standards, policies, practices, and agreements reasonably calculated to ensure, to the greatest extent practicable and permitted by law, that the certified EHR technology was, at all relevant times: (1) Connected in accordance with applicable law; (2) compliant with all standards applicable to the exchange of information, including the standards, implementation specifications, and certification criteria adopted at 45 CFR part 170; (3) Implemented in a manner that allowed for timely access by patients to their electronic health information; and (4) Implemented in a manner that allowed for the timely, secure, and trusted bi-directional exchange of structured electronic health information with other health care providers (as defined by 42 U.S.C. 300jj(3)), including unaffiliated providers, and with disparate certified EHR technology and health IT vendors.
	  ○ Statement C: Responded in good faith and in a timely manner to requests to retrieve or exchange electronic health information, including from patients, health care providers (as defined by 42 U.S.C. 300jj(3)), and other persons, regardless of the requestor's affiliation or technology vendor.
	• Beginning with the CY 2022 performance period/CY 2024 MIPS payment year, CMS is proposing to no longer

	require an application for clinicians and small practices seeking to qualify for the small practice hardship exception and reweighting • Proposing instead to assign a weight of zero percent to the Promoting Interoperability performance category and redistribute its weight to another performance category or categories (as discussed further in section IV.A.3.e. of this proposed rule) in the event no data is submitted for any of the measures for the Promoting Interoperability performance category by or on behalf of a MIPS eligible clinician in a small practice • Proposing that if data is submitted for a MIPS eligible clinician in a small practice, they would be scored on the Promoting Interoperability performance category like all other MIPS eligible clinicians, and the performance category would be given the weight prescribed by section 1848(q)(5)(E) of the Act • Proposing the small practice significant hardship exception still would be subject to annual renewal, and we would verify whether a practice meets the definition of a small practice under § 414.1305 on an annual basis • It is not CMS' intention that this policy be in place for the long term, but rather only for a few years, as CMS would like to increase participation of small practices in the Promoting Interoperability performance category • Seeking comment on why small practices that have not successfully reported for the Promoting Interoperability performance category not applied for the small practice hardship exception • Also interested in hearing about barriers that exist that prevent the adoption of CEHRT and/or the ability to submit Promoting Interoperability performance category measures • Proposing that in the case of an APM Entity that also meets the definition of a small practice, we would continue applying the Promoting Interoperability performance category reporting and exception requirements at the group level o However, if the APM Entity is composed of a single TIN which itself meets the definition of a small practice, all TINs within the APM Entity (that is, the single TIN) would be eligible for this exception, and therefore the Promoting Interoperability performance category would be reweighted for the APM Entity and the performance category reweighting described above would be applied • Requesting comments as to whether Nurse Practitioners, Physician Assistants, Clinical Nurse Specialists, and Certified Registered Nurse Anesthetists are using CEHRT and are able to submit data on the measures for the Promoting Interoperability performance category o Proposing to continue the existing policy - reweighting the category for these professionals to zero if they do not report - for the 2022 performance period/2024 MIPS payment year\ • Proposing to continue the existing policy of reweighting the Promoting Interoperability performance category for physical therapists, occupational therapists, qualified speech-language pathologist, qualified audiologists, clinical psychologists, and registered dieticians or nutrition professionals for the 2022 performance period/2024 MIPS payment year • Proposing to add clinical social workers and certified nurse-midwives to the definition of a MIPS eligible clinician o For the CY 2022 performance period/CY 2024 MIPS payment year, CMS is proposing to apply the same Promoting Interoperability reweighting policy we adopted previously for NPs, PAs, CNSs, CRNAs, and other types of MIPS eligible clinicians to clinical social workers as we believe that there may not be sufficient Promoting Interoperability performance category measures that are applicable and available to clinical social workers o Requesting comment on whether there are in fact sufficient measures applicable and available to certified nurse-midwives under the Promoting Interoperability performance category, and whether barriers exist that prevent certified nurse-midwives from complying with the requirements of the Promoting Interoperability performance category and may warrant reweighting

Advancing to Digital Quality Measurement and the Use of Fast Healthcare Interoperability Resources (FHIR) in Physician Quality Programs – Request for Information	• Seek input on future elaboration that would define a dQM as a software that processes digital data to produce a measure score or measure scores
	• Seek feedback on how leveraging advances in technology (for example, FHIR APIs) to access and electronically transmit interoperable data for dQMs could reinforce other activities to support quality measurement and improvement (for example, the aggregation of data across multiple data sources, rapid-cycle feedback, and alignment of programmatic requirements).
	• CMS will continue to consider how to leverage the interoperability advantages offered by the FHIR standards and API-based data submission, including digital quality measurement
	• CMS is considering further modernization of the quality measurement enterprise in four major ways: (1) Leverage and advance standards for digital data and obtain all EHR data required for quality measures via provider FHIR-based APIs; (2) redesign our quality measures to be self-contained tools; (3) better support data aggregation; and (4) work to align measure requirements across our reporting programs, other federal programs and agencies, and the private sector where appropriate
	• CMS is considering targeting the data required for our quality measures that utilize EHR data to be data retrieved via FHIR-based APIs based on standardized, interoperable data
	• CMS is considering methods and approaches to leverage the interoperability data requirements for APIs in certified health IT set by the ONC 21st Century Cures Act final rule to support modernization of CMS quality measure reporting
	• Seeking feedback on the goal of aligning data needed for quality measurement with interoperability requirements and the strengths and limitations of this approach
	• Seeking feedback on the importance of and approaches to supporting inclusion of PGHD and other currently non-standardized data
	• Considering approaches for including quality measures that take advantage of standardized data and interoperability requirements that have expanded flexibility and functionality compared to CMS' current eCQMs
	• Considering defining and developing dQM software as end-to-end measure calculation solutions that retrieve data from primarily FHIR-based resources maintained by providers, payers, CMS, and others; calculate measure score(s), and produce reports
	• CMS believes to optimize the use of standardized and interoperable data, the software solution for dQMs should do the following:
	  ○ Have the flexibility to support calculation of single or multiple quality measure(s).
	  ○ Perform three functions-- Obtain data via automated queries from a broad set of digital data sources (initially from EHRs, and in the future from claims, PRO, and PGHD); Calculate the measure score according to measure logic; and Generate measure score report(s).
	  ○ Be compatible with any data source systems that implement standard interoperability requirements.
	  ○ Exist separately from digital data source(s) and respect the limitations of the functionality of those data sources.
	  ○ Be tested and updated independently of the data source systems.
	  ○ Operate in accordance with health information protection requirements under applicable laws and comply with governance functions for health information exchange.
	  ○ Have the flexibility to be deployed by individual health systems, health IT vendors, data aggregators, and health plans; and/or run by CMS depending on the program and measure needs and specifications.
	  ○ Be designed to enable easy installation for supplemental uses by medical professionals and other non-technical end-users, such as local calculation of quality measure scores or quality improvement.
	  ○ Have the flexibility to employ current and evolving advanced analytic approaches such as natural language processing.

	○ Be designed to support pro-competitive practices for development, maintenance, and implementation, as well as diffusion of quality measurement and related quality improvement and clinical tools through, for example, the use of open-source core architecture. • Seek comment on these suggested functionalities and other additional functionalities that quality measure tools should ideally have particularly in the context of the possible expanding availability of standardized and interoperable data (for example, standardized EHR data available via FHIR-based APIs) • Also interested whether and how this more open, agile strategy may facilitate broader engagement in quality measure development, the use of tools developed for measurement for local quality improvement, and/or the application of quality tools for related purposes such as public health or research • CMS is considering expanding and establishing policies and processes for data aggregation and measure calculation by third-party aggregators that include, but are not limited to, HIEs and clinical registries • Seek feedback on aggregation of data from multiple sources to inform measurement and potential policy considerations • Seek feedback on the role data intermediaries can and should play in CMS quality measure reporting in collaboration with providers, and how we can best facilitate and enable aggregation • CMS is committed to using policy levers and working with stakeholders to solve the issue of interoperable data exchange and to transition to full digital quality measurement • CMS is considering the future potential development and multi-staged implementation of a common portfolio of dQMs across our regulated programs, agencies, and private payers • CMS would coordinate closely with quality measure developers, federal and state agencies, and private payers to develop and to maintain a cohesive dQM portfolio that meets our programmatic requirements and that fully aligns across federal and state agencies and payers to the extent possible • Seek feedback on initial priority areas for the dQM portfolio given evolving interoperability requirements (for example, measurement areas, measure requirements, tools, and data standards) • Seek to identify opportunities to collaborate with other federal agencies, states, and the private sector to adopt standards and technology-driven solutions to address our quality measurement priorities across sectors • CMS outlines specific questions for this RFI beginning on page 690
Closing the Health Equity Gap in CMS Clinician Quality Programs—Request for Information (RFI)	• CMS is committed to achieving equity in health care outcomes for Medicare beneficiaries by supporting providers in quality improvement activities to reduce health inequities, enabling them to make more informed decisions, and promoting provider accountability for health care disparities • CMS has been considering, among other things, expanding our efforts to provide stratified data for additional social risk factors and measures, optimizing the ease-of-use of the results, enhancing public transparency of equity results, and building towards provider accountability for health equity • Seeking public comment on two potential future expansions of the CMS Disparity Methods, including: (1) future potential stratification of quality measure results by race and ethnicity, and (2) improving demographic data collection • Two algorithms have been developed to indirectly estimate the race and ethnicity of Medicare beneficiaries • The use of indirect estimated race and ethnicity for conducting stratified reporting does not place any additional collection or reporting burdens on hospitals as these data are derived using existing administrative and census-linked data • CMS is interested in learning about, and are soliciting comments on, current data collection practices by hospitals to capture demographic data elements (such as race, ethnicity, sex, sexual orientation and gender identity (SOGI), language preference, tribal membership, and disability status) • Also interested in potential challenges facing clinicians with collecting a minimum set of demographic data

	elements in alignment with national data collection standards (such as the standards finalized by the Affordable Care Act) and standards for interoperable exchange (such as the United States Core Data for Interoperability incorporated into certified health IT products as part of the 2015 Edition of health IT certification criteria) • Seek comments on other efforts we can take within the MIPS program to further bridge the equity gap
Health Equity Measures in MVPs- Request for Information (RFI)	• CMS requests information on the following: o Should health equity measures be developed in a manner to be broadly applicable to the various specialties and subspecialties that participate in MIPS? o Is there value in the development of more specialty specific health equity measures? o Considering MIPS and MVPs includes several specialties and subspecialties, what factors should be considered when developing a health equity measure? o Should we include a health equity measure in the foundational layer of all MVPs, as a required measure, in the future? If not, why not?
Request for Information on Additional Objectives Adopting FHIR®-based API Standards	• CMS is seeking comments on their intention to align additional Promoting Interoperability performance category objectives with approaches utilizing HL7®FHIR® standard Release 4-based API functionality (or the appropriately evolved standard), specifically targeting the Health Information Exchange as well as the Public Health and Clinical Data Exchange objectives. • CMS is interested in public comments on how these two program objectives could be furthered through the use of FHIR®-based API solutions. o Specifically, they are interested in the following questions: ▪ To what degree are stakeholders currently using or interested in using APIs to exchange information in support of the numerator/denominator measures under the HIE objective? ▪ What revisions to the measures under the HIE objective should CMS explore to facilitate use of standards-based APIs in health IT modules certified under the 2015 Edition Cures Update? ▪ How could technical approaches utilizing the FHIR® standard enhance existing data flows required under the public health measures? ▪ What are promising FHIR®-based approaches to public health reporting use cases that ONC and CMS should explore for potential future consideration as part of the Promoting Interoperability performance category and the ONC Health IT Certification Program? ▪ To what degree are PHAs and individual states currently exploring API-based approaches to conducting public health registry reporting? ▪ What other factors do stakeholders see as critical factors to adopting FHIR®-based approaches? ▪ What potential policy and program changes in CMS and other HHS programs could reduce health care provider and health IT developer burden related to measures under the Health Information Exchange and the Public Health and Clinical Data Exchange objectives?
Request for Information on Clinical Notes	• CMS is seeking stakeholder feedback on changes we can make that will better support the goals of the OpenNotes movement to ensure that clinical notes are widely available to patients. o Given the implementation of updates to certified technology described above that support the Provide Patients Access to their Health Information measure, are there additional changes to this measure, or other program guidance, which could further facilitate ensuring clinical notes are available to patients consistent with the goals of the OpenNotes movement? • CMS is seeking feedback on the development of a required and independently scored measure for the

	Promoting Interoperability performance category to allocate points for the use of “clinical note” types supported by certified health IT • CMS is seeking comment on the types of clinical notes that are commonly sought, but not easily accessible to patients.