Wynne Health Group

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FEDERAL HEALTH IT POLICY: PROMOTING INTEROPERABILITY

I. INTRODUCTION

This brief provides an overview of federal health information technology (health IT) policy, beginning with the evolution of the Centers for Medicare and Medicaid Services' (CMS) Promoting Interoperability Programs, formerly the Medicare and Medicaid Electronic Health Record Incentive Programs (EHR Incentive Programs) (section II).

Next, the issue brief expounds upon the Medicare and Medicaid Promoting Interoperability requirements delineated of clinicians in the Quality Payment Program (QPP) and for hospitals (sections III and IV). In section V, we discuss the recently-promulgated interoperability and information blocking proposed regulations, including key payer- and provider-related provisions. Finally, we turn to key Congressional developments on the health IT front, including prospects for potential health IT-related legislation, as well as broader Congressional oversight of the 21st Century Cures Act (Cures Act) health IT provisions.

II. EVOLUTION OF THE PROMOTING INTEROPERABILITY PROGRAMS

In 2011, pursuant to the Health Information Technology for Economic and Clinical Health Act (HITECH Act), CMS established the EHR Incentive Programs, later renaming it to the "Promoting Interoperability Programs" in April 2018.[1] The rebranding marked CMS' shift from implementing existing meaningful use requirements to "an increased focus on interoperability and improving patient access to health information."[2]

The HITECH Act authorized CMS to provide Medicare and Medicaid EHR incentive payments to eligible professionals (EPs) (now deemed eligible clinicians, or ECs); eligible hospitals; and critical access hospitals (CAHs) to encourage the adoption and meaningful use of certified electronic health record technology (CEHRT). The initial framework outlined a three-stage trajectory toward meaningful use of CEHRT – moving from data capture and sharing (Stage 1); to advance clinical processes (modified Stage 2); to the present-day focus of improving outcomes (Stage 3).

[1] https://www.govinfo.gov/content/pkg/FR-2018-05-07/pdf/2018-08705.pdf
[2] https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/index.html?redirect=/EHRincentiveprograms

Medicare EHR incentive payments for ECs, hospitals and CAHs ended in 2016; after which time, downward payment adjustments were imposed on providers failing to demonstrate meaningful use.[3] However, pursuant to the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), Medicare EHR payment adjustments for ECs sunset in 2018. In its place, Congress authorized the transition to a new clinician value-based payment program, the Quality Payment Program (QPP), the latter of which incorporates aspects of meaningful use. CMS is currently in Year 3 (2019) of the QPP (implicating payment in 2021), as detailed more fully in section III.

Meanwhile, Medicaid EHR incentive payments for ECs, eligible hospitals and CAHs were slated to end in 2016; however, subsequent legislation extended Medicaid incentive payments through 2021.[4] Note that, unlike Medicare, there are no downward payment adjustments imposed in the Medicaid PI Program.[5]

III. QPP

With the passage of MACRA, Congress put an end to the 17-year trajectory of stop-gap "doc fixes" to prevent statutorily-slated cuts to Medicare physician payments otherwise called for by the Sustainable Growth Rate (SGR) formula.[6]

Pursuant to the MACRA, on January 1, 2017, CMS launched the Quality Payment Program (QPP), establishing two tracks for clinician payment, both of which incorporate elements of meaningful use: (1) participation in the Merit-based Incentive Payment System (MIPS); or (2) participation in an advanced alternative payment model (APM).[7] The QPP is intended to move clinicians toward value-based care, while streamlining legacy clinician quality and cost reporting programs (e.g., the Physician Quality Reporting System (PQRS) and the Value-based Payment Modifier (VM)).

Beginning in Calendar Year (CY) 2020, per the MACRA, Medicare physician fee schedule (MPFS) payments are scheduled to flatline for 2020-2025 before beginning to increase again, albeit in divergent ways for clinicians participating in MIPS (0.25 percent fee schedule update/year) and APMs (0.75 percent fee schedule update/year). In the interim period, however, respective APM bonus payments (5 percent annual bonus payment over the CY 2019-2024 period) and positive/negative MIPS payment adjustments (through CY 2025) continue to apply.

[3] https://www.cms.gov/newsroom/fact-sheets/2018-medicare-electronic-health-record-ehr-incentive-program-payment-adjustment-fact-sheet-eligible and https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Eligible_Hospital_Information.html
[4] https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/Medicaid_PaymentScheduleEP.pdf
[5] https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Eligible_Hospital_Information.html
[6] https://www.healthaffairs.org/do/10.1377/hblog20150415.046932/full/
[7] https://www.cms.gov/Medicare/Quality-Payment-Program/Quality-Payment-Program.html

A. MIPS

CMS continues clinicians' "gradual transition" to MIPS pursuant to the program's initial "pick your pace" launch and the latest flexibility in this vein authorized by the Bipartisan Budget Act of 2018 (BBA).[8] For the 2019 MIPS performance period (Year 3) the corresponding (positive or negative) payment adjustment in CY 2021 is (+/-) 7 percent.[9]

Under MIPS, clinicians are evaluated based on four weighted performance categories that contribute to an overall "composite performance score" affecting payment in future years. The four performance categories are: (1) Quality, which replaced PQRS (45 percent weight of final score); (2) Promoting Interoperability (formerly Advancing Care Information (ACI)), which replaced the Medicare EHR Incentive Program (25 percent weight of final score); (3) Improvement Activities (15 percent weight of final score); and (4) Cost, which replaced the VM program (15 percent weight of final score).[10]

Certain clinician types are required to participate in MIPS for the 2019 Performance Year (PY) if they exceed the low-volume threshold, are enrolled in Medicare prior to January 1, 2019 and are not otherwise deemed to be a Qualifying APM Participant (QP) or Partial QP (detailed below). In addition to physicians, nurse practitioners and other MIPS-eligible clinician types delineated by the MACRA, newly-eligible clinicians in the third year of MIPS include: physical therapists, occupational therapists, speech-language pathologists, audiologists, clinical psychologists, and registered dietitians or nutrition professionals.[11]

The low-volume threshold (LVT) is set over a 12-month "MIPS determination period" that considers whether a clinician: bills more than $90,000 in Part B-covered professional services *and* sees more than 200 Part B patients *and* provides 200 or more covered professional services to Part B patients. Clinicians may participate in MIPS as an individual; or as part of a practice group or defined virtual group.[12] However, some physician stakeholders, along with the House GOP Doctors Caucus[13], contend that CMS' LVT has excluded roughly 60 percent of otherwise eligible clinicians for the 2019 performance year, "effectively collaps[ing] the MIPS payment adjustment distribution curve" for higher performers.[14]

Further, the Medicare Payment Advisory Commission (MedPAC) voiced concerns regarding the basic design of MIPS, indicating it is fundamentally incompatible with the goals of a beneficiary-focused approach to quality measurement. In its March 2018 report to Congress, the Commission recommended that MIPS be eliminated as soon as possible and replaced by a new clinician value-based purchasing program within Medicare fee-for-service (FFS).[15]

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[8] https://www.govinfo.gov/content/pkg/FR-2018-11-23/pdf/2018-24170.pdf
[9] See "2019 MIPS Participation and Eligibility Fact Sheet" available at https://qpp.cms.gov/about/resource-library. See also: https://365.himss.org/sites/himss365/files/365/handouts/552803478/handout-44.pdf?_ga=2.130412175.1068637322.1554303052-1117869872.1554303052
[10] https://qpp.cms.gov/mips/overview
[11] https://qpp.cms.gov/participation-lookup/about?py=2019
[12] https://qpp.cms.gov/mips/overview
[13] http://www.amga.org/wcm/Advocacy/Issues/MACRA/20180703.pdf
[14] http://www.amga.org/wcm/AboutAMGA/News/2018/20180705.aspx
[15] https://mypolicyhub.com/content_entry/commission-releases-march-2018-report-to-congress-with-medicare-2019-payment-update-recommendations-mips-telehealth-addressed/

B. APMs

CMS defines APMs as a "[p]ayment approach that gives added incentive payments to provide high-quality and cost-efficient care. APMs can apply to a specific clinical condition, a care episode, or a population." Eligible clinicians and groups participating in "Advanced APMs" – a medical home model expanded under CMS Innovation Center authority or a significant risk-bearing participant – are eligible for a 5 percent incentive payment for achieving specified thresholds. Further, Advanced APMs must also ensure that at least 75 percent of the clinicians in an APM entity use CEHRT (PY 2019 requirement).[16] Note, though, that requirements surrounding use of EHR technology are specific to each model, and many have requirements exceeding this baseline. For Advanced APMs that are hospitals, each hospital must use CEHRT.[17]

Advanced APMs meeting the above requirements are deemed QPs and are excluded from the MIPS reporting requirements and payment adjustment. Beginning this year (PY 2019), CMS authorizes ECs participating in a combination of Advanced APMs with Medicare and Other-Payer Advanced APMs to become a QP. In contrast to QPs, Partial QPs participate in Advanced APMs if they meet (lower) specified participation thresholds may elect whether to participate in MIPS.[18]

IV. CURRENT PROMOTING INTEROPERABILITY STANDARDS

A. CLINICIANS – QPP: YEAR 3

The CY 2019 MPFS final rule delineates policies pertaining to Year 3 (CY 2019) of the MIPS Promoting Interoperability performance category.[19] For MIPS reporting during Year 3, 2015 Edition CEHRT is required for MIPS eligible clinicians, which as discussed above, include an expanded cohort of clinician types (e.g., physical therapists, occupational therapists, etc.).[20]

As addressed above, the Promoting Interoperability performance category is weighted at 25 percent of a clinician's final performance score, as it was under the previous ACI category. ECs must report on measures across four objectives: (1) Electronic Prescribing (eRx); (2) Health Information Exchange (HIE); (3) Provider to Patient Exchange; and (4) Public Health and Clinical Data Exchange – for 90 continuous days or more. Extra percentage points may be awarded for meeting the Public Health and Clinical Data Registry Reporting objective.

CMS also finalized hardship exemptions for clinicians pursuant to new statutory authority under the Cures Act. A clinician or group participating in MIPS may submit a Promoting Interoperability Hardship Exception Application, citing one of the following reasons for review and approval: (1) MIPS eligible clinician in a small practice; (2) MIPS eligible clinician using decertified EHR technology; (4) Insufficient

[16] https://qpp.cms.gov/apms/advanced-apms?py=2019
[17] https://www.healthit.gov/sites/default/files/macra_health_it_fact_sheet_final.pdf
[18] https://qpp.cms.gov/apms/advanced-apms?py=2019
[19] https://www.federalregister.gov/documents/2018/11/23/2018-24170/medicare-program-revisions-to-payment-policies-under-the-physician-fee-schedule-and-other-revisions
[20] Ibid.

Internet connectivity; (5) Extreme and uncontrollable circumstances; or (5) Lack of control over the availability of CEHRT. Claiming a hardship exception means that the Promoting Interoperability performance category receives 0 weight in calculating the clinician's final score and the 25 percent is reallocated to the quality performance category.[21]

B. HOSPITALS

In the FY 2019 Medicare Inpatient Prospective Payment System (IPPS) and Long-Term Acute Care Hospital (LTCH) Prospective Payment System (PPS) final rule, CMS finalized policies to overhaul the Promoting Interoperability Programs for hospitals largely in alignment with changes under the MPFS. This included new performance-based scoring methodology consisting of a smaller set of objectives that provide a more flexible, less burdensome structure.

The FY 2019 IPPS/LTCH final rule delineated an EHR reporting period of a minimum of any continuous 90-day period in each of CYs 2019 and 2020. Additionally, eligible hospitals and CAHs are required to use the 2015 Edition CEHRT and must report on certain measures across each of the four objectives addressed above for ECs, namely: (1) eRx; (2) HIE; (3) Provider to Patient Exchange; and (4) Public Health and Clinical Data Exchange – with performance-based scoring occurring at the individual measure-level.[22]

Scores on each individual measure contribute to an overall Promoting Interoperability score of up to 100 possible points for each eligible hospital or CAH. A total score of 50 points or more will satisfy the requirement to report on the objectives and measures of meaningful use, which is one of the requirements for an eligible hospital or CAH to be considered a meaningful EHR user and avoid a negative Medicare payment adjustment.

For both clinicians in the QPP and hospitals, recent rulemaking added two new bonus measures under the eRx objective: (1) Query of the Prescription Drug Monitoring Program (PDMP); and (2) Verify Opioid Treatment Agreement. CMS notes that these align with its broader goals surrounding the opioid epidemic. The latter measure is optional to report on for both 2019 and 2020, while the former measure will become mandatory beginning in 2020.[23]

V. INTEROPERABILITY, INFORMATION BLOCKING PROPOSALS

On February 11, 2019, CMS and the Office of the National Coordinator for Health Information Technology (ONC) released much-anticipated parallel proposed rules intended to advance interoperability, limit instances of information blocking, and facilitate the exchange of electronic health information (EHI). Both

[21] https://qpp.cms.gov/mips/promoting-interoperability?py=2019
[22] https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/ScoringMeth_FactSheet-.pdf
[23] https://www.federalregister.gov/documents/2018/08/17/2018-16766/medicare-program-hospital-inpatient-prospective-payment-systems-for-acute-care-hospitals-and-the

rules codify provisions that stem from the Cures Act and are pursuant to broader policies delineated in the President's 2017 Executive Order on Promoting Healthcare Choice and Competition.[24]

A. CMS' Interoperability Proposal

CMS' proposed rule on interoperability and patient access primarily seeks to define health IT interoperability and implement requirements across payers and providers to promote the sharing of information. The ultimate aim is to better ensure patients have timely access to their EHI to support health care decision-making, while facilitating seamless care coordination.[25] The rule would accomplish this by requiring payers and providers to ensure their health IT systems are able to share patient health information between one another without undue burden.

1. Key Payer-related Provisions

For payers, the proposal requires the development and implementation of application programming interfaces (APIs) akin to the Blue Button 2.0 API implemented in Medicare FFS. Such an interface allows Medicare beneficiaries "to access their health information electronically through the application of their choosing," which are developed by third-party entities. As this already exists in Medicare FFS, the rule would extend this requirement to Medicare Advantage (MA) plans; the Medicaid and Children's Health Insurance Program (CHIP); Medicaid managed care organizations (MCOs); and Qualified Health Plans (QHP) in federal Exchanges.

Payers would also be required to support the electronic exchange of information for transitions of care as enrollees move between plans. Such information would include diagnoses, procedures, tests, providers the beneficiary has seen, and utilization levels. In addition to ensuring clinicians have access to the necessary information to provide value-added, non-redundant, and coordinated care, CMS estimates this provision would provide 125 million individuals access to their health information.[26]

2. Key Provider-related Provisions

A key change for providers comes through a proposed modification to the conditions of participation (CoPs) for Medicare-participating hospitals and CAHs. In order to participate in Medicare and Medicaid, this change would require hospitals to generate notifications to other providers when a beneficiary is admitted to the hospital, discharged, or transferred (ADT notifications).

The proposed rule would also require individual providers and hospitals to publicly attest to whether they participated in information blocking activities, requiring that they perform this attestation to receive full Medicare reimbursement. CMS expects that making this information publicly available would encourage

[24] https://www.whitehouse.gov/presidential-actions/presidential-executive-order-promoting-healthcare-choice-competition-across-united-states/
[25] https://www.federalregister.gov/documents/2019/03/04/2019-02200/medicare-and-medicaid-programs-patient-protection-and-affordable-care-act-interoperability-and
[26] https://www.federalregister.gov/documents/2019/03/04/2019-02200/medicare-and-medicaid-programs-patient-protection-and-affordable-care-act-interoperability-and

providers to avoid information blocking schemes. Last, CMS proposes the creation of a "centralized directory of provider electronic addresses for data exchange," which CMS expects would make data exchange across providers more efficient. CMS would also make publicly available the information of providers who do not provide the requested information.

B. ONC's Information Blocking Proposal

In support of interoperability, the ONC proposed rule seeks to implement provisions from the Cures Act that establish a series of exceptions to the definition of information blocking. In short, ONC defines information blocking as when "a person or entity – typically a health care provider, information technology (IT) developer, or EHR vendor – knowingly and unreasonably interferes with the exchange and use of electronic health information."[27] Examples of information blocking include charging excessive fees that deter users from accessing health information or using non-standard technology that prevents information sharing.

ONC acknowledges that certain situations reasonably require actions that could constitute information blocking. As such, the agency proposes seven scenarios in which it would be permissible to engage in information blocking. These scenarios include, for example, when sharing information would result in patient harm; when it is necessary to protect patient privacy; and, when health IT developers or providers charge reasonable fees to recover the costs incurred from developing health IT systems, among others.

Also included in the proposal is a series of updates to the 2015 Edition CEHRT. These specify the capabilities, standards, and implementation specifications required for health IT to receive certification for use in a CMS program. One prominent change included in this update is a measure that would remove the Common Clinical Data Set (CCDS) as a basis for governing which data is included in interoperable exchange, replacing it with the United States Core Data for Interoperability (USCDI). This would increase the baseline of data classes that must be included for interoperable exchange, expanding requirements to include key clinical notes by providers, patient addresses and phone numbers, and pediatric vital signs. ONC notes this will be important as health care continues to move to a value-based system.

Additionally, the proposed rule offers changes that are specific to pediatric populations. Specifically, the rule proposes 10 requirements for voluntary certification of health IT in the pediatric setting, delineating the types of data these systems must capture. The recommended criteria include requirements such as whether the health IT system is able to compute weight-based drug dosage; whether it is able to document all guardians and caregivers; and whether it can track incomplete preventative care opportunities, among others. ONC further proposes using the 2015 Edition CEHRT and certain new criteria to facilitate implementation of the aforementioned recommendations.

C. Stakeholder Feedback and Potential Next Steps

Organizations ranging from health plans, providers, patient groups, and health IT firms expressed support for CMS and ONC's interoperability proposals, including changes that may limit reimbursement for

[27] https://www.healthit.gov/topic/information-blocking

providers failing to comply with certain new requirements.[28] Others, such as the Healthcare Information and Management Systems Society (HIMSS), endorse specific provisions, such as the adoption of 2015 Edition criteria to facilitate interoperability.[29] HIMSS also recommends that opioid-related measures be more outcomes-focused, and suggested the need for greater emphasis on public health measures within interoperability programs.

On the other hand, certain stakeholders from the hospital and provider community have raised concerns with regard to unintended burden caused by certain proposals such as the requirements on hospitals to supply ADT notifications as a Medicare and Medicaid CoP.[30, 31]

CMS and ONC solicit feedback on the rules through May 3, 2019. Following the agencies' consideration of comments, the rules may be finalized as early as this fall/winter. Early indications of public support from various stakeholders suggest that the rules may remain largely intact conceptually, as proposed, though some of the specific considerations offered by industry stakeholders may provide insight into how the finalized policies may differ from the wide-ranging proposals.

VI. RECENT CONGRESSIONAL HEALTH IT DEVELOPMENTS

Since the passage of the Cures Act in 2016, Congress continues to engage on issues regarding interoperability. Most recently, last March, the Senate Health, Education, Labor and Pensions (HELP) Committee held an oversight hearing to review implementation of Cures Act-mandated EHI provisions.[32] While members expressed overall support for the proposed rules released by CMS and ONC, patient privacy emerged as a bipartisan concern.

For example, HELP Ranking Member Patty Murray (D-WA) expressed intereste in potential risks associated with health information accessed through third-party applications not covered by HIPAA as well as with the sale of data. Senator Bill Cassidy (R-LA) raised issue with patients unable to access or "own their data," available to health insurance plans. Additionally, HELP Committee Chairman Lamar Alexander (R-TN) questioned the pace of implementation, noting he had "urged the Obama Administration to slow down the Meaningful Use program in 2015."[33]

On the House side, last December, Dr. Donald Rucker, the National Coordinator for Health Information Technology, appeared before the Energy and Commerce Health Subcommittee to discuss Cures Act implementation.[34] Members were particularly interested in rulemaking to address interoperability and

[28] https://s3.amazonaws.com/assets.fiercemarkets.net/public/004-Healthcare/external_Q22018/Sign+On+Letter+Supporting+Use+of+CoPs.pdf
[29] https://www.himss.org/sites/himssorg/files/u393098/HIMSS-2019-IPPS-NPRM-Comment-Letter.pdf
[30] https://ehrintelligence.com/news/aha-opposes-key-information-blocking-regulation-in-cms-proposed-rule
[31] https://chimecentral.org/wp-content/uploads/2018/06/CHIME-Letter-to-CMS-on-IPPS-proposed-rule-for-2019.pdf
[32] https://www.help.senate.gov/hearings/implementing-the-21st-century-cures-act-making-electronic-health-information-available-to-patients-and-providers
[33] https://www.alexander.senate.gov/public/index.cfm?p=SpeechesFloorStatements&id=17AE9CA2-37FA-4D15-81D7-B35F3016D293
[34] https://energycommerce.house.gov/committee-activity/hearings/hearing-on-implementing-the-21st-century-cures-act-an-update-from-the

information blocking. They also highlighted other areas of concern, including administrative burden, physician burnout, cybersecurity, patient education, and mobile health applications.

Finally, last January, pursuant to the Cures Act, the Government Accountability Office (GAO) released a report highlighting challenges and solutions related to patient record matching. Some of the recommendations offered to improve matching entailed standardizing patients' demographic data records in health IT systems; and utilizing a "national unique patient identifier" among other solutions.[35]

We anticipate that Congressional panels will continue oversight of the Cures Act interoperability and information blocking provisions, particularly now that the CMS and ONC rules have been promulgated. Additionally, some of the aforementioned policy solutions raised in the GAO's recent health IT report and the context of Congressional hearings may serve as a starting point for future legislation on health IT.

VII. CONCLUDING REMARKS

We anticipate that Congressional panels will continue oversight of the Cures Act interoperability and information blocking provisions, particularly now that the CMS and ONC rules have been promulgated. Additionally, some of the aforementioned policy solutions raised in the GAO's recent health IT report and in the context of Congressional hearings may serve as a starting point for future legislation on health IT – albeit in an "opioids 2.0" bill or other moving legislative vehicle this Congress.

In the meantime, CMS and ONC are accepting comments on its interoperability and information blocking proposals through early May, after which final regulations may be issued as early as this fall/winter. As always, WHG will continue to keep you apprised of key developments on this front. Please do not hesitate to reach out to our team with questions.

[35] https://www.gao.gov/assets/700/696426.pdf