CMS PROPOSES CHANGES TO MEDICARE SHARED SAVINGS PROGRAM

Date: 12 August 2016

Health Care Alert

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On July 7, 2016, the Centers for Medicare & Medicaid Services ("CMS") issued a proposed rule that updates payment policies, rates, and quality provisions for services furnished under the Medicare Physician Fee Schedule for calendar year 2017 (the "Proposed Rule")._ftn1 Notably, the Proposed Rule also includes several changes to the Medicare Shared Savings Program ("MSSP"), which are the subject of this Alert. As outlined in more detail below, CMS proposes:

- To update MSSP quality measures and align MSSP with the Quality Payment Program ("QPP") under the Medicare Access and CHIP Reauthorization Act of 2015 ("MACRA").
- To provide an option for consideration of beneficiary preferences for purposes of assignment to an Accountable Care Organization ("ACO").
- To add beneficiary protections when ACOs use the MSSP skilled nursing facility ("SNF") 3-day waiver rule.

Public comments on the Proposed Rule are due by September 6, 2016.

QUALITY REPORTING CHANGES

Changes to MSSP quality measure set.

The Proposed Rule includes several changes to the quality measures set currently used under MSSP. In particular, the changes are designed to align the MSSP quality measures with the measures recommended by the Core Quality Measures Collaborative, a joint effort led by America's Health Insurance Plans and its member plans, CMS, the National Quality Forum, physician organizations, and others to reach consensus on core performance measures for payors to use for quality reporting purposes._ftn2 The changes are also designed to align with the proposed reporting requirements under the QPP proposed rule, which consolidates portions of three existing quality reporting programs under a single system, among other changes._ftn3 Accordingly, CMS proposes to add, modify, remove, or replace several quality measures from MSSP.[4]

Changes to quality validation audits.

Under current MSSP rules, CMS retains the right to validate the quality data ACOs submit to the agency through an audit process. Through this process, CMS selects a subset of quality measurements and a random sample of 30 beneficiary records for each measure. The agency then calculates a measure-specific audit performance rate

based on a multi-phased approach that closely examines eight records for each measure to determine if the documentation supports reported performance (a "match" in CMS's terminology), then proceeds to the other 22 records if a mismatch appears. For each measure with a match rate of less than 90%, CMS educates the ACO and provides an opportunity to resubmit the data. However, at the conclusion of this process, if there is a discrepancy greater than 10%, the ACO is not given credit for meeting the target for that particular quality measure._ftn5

CMS proposes several modifications to this process. First, CMS would increase the number of records audited per quality measure. CMS does not anticipate it will request more than 50 records per audited measure, although it notes that the precise number of records would vary depending on the desired confidence level, the number of measures audited, and the expected match rate. Second, CMS would conduct the quality validation audit in a single step, rather than the multi-phased approach under the current program, and would no longer provide an opportunity to resubmit records at the conclusion of the audit._ftn6 Third, CMS proposes to assess each ACO's overall match rate across all quality measures rather than the current approach that looks at the match rate for each individual quality measure. If an ACO fails the audit, the ACO's overall quality score would then be adjusted in proportion to its audit performance. For example, if an ACO's quality score is 75% and its audit match rate is 80%, the ACO's audit-adjusted quality score would be 60% — that is, 80% of the 75% total quality score. Finally, CMS proposes that if an ACO has an audit match rate of less than 90%, it may be required to submit a corrective action plan ("CAP") for CMS approval._ftn7 The CAP could be imposed in lieu of or in addition to CMS's existing authority to terminate or impose other sanctions on an ACO that does not properly report quality data.

Revisions to permit providers in ACOs to report quality apart from the ACO under limited circumstances.

Current regulations prohibit ACO participant TINs and the providers billing through those TINs from participating in the PQRS outside of MSSP, such that these entities/providers may not independently report for purposes of PQRS apart from the ACO in which they are participating. In the Proposed Rule, CMS would change this policy to accept and use data that is separately reported outside the ACO under limited circumstances. In particular, for 2017 and 2018 — the final two years of PQRS before the program sunsets and is replaced by QPP — if an ACO does not satisfactorily report quality data for purposes of PQRS, CMS may accept and use data that is reported outside the ACO._ftn8 CMS also proposes to permit a similar process upon implementation of the QPP.

Updates to align MSSP with PQRS and QPP.

The Proposed Rule also contains several provisions to align MSSP with the QPP proposed under MACRA earlier this year and the programs QPP would replace.

For example, CMS proposes changing existing regulations to specify that the final reporting period for PQRS and the EHR incentive program would be 2016._ftn9 Beginning in 2017, quality reporting will occur through the QPP.

CMS also includes new rules addressing the annual assessment of an ACO Eligible Clinicians' ("ECs") use of Certified Electronic Health Record Technology ("CEHRT") and ACO reporting of quality measures. Under MACRA, one performance criterion for purposes of eligibility for bonus payments associated with participating in an Advanced Alternative Payment Model ("APM") measures the use of CEHRT among the ECs providing services

under the Advanced APM. As part of the MACRA proposed rule, CMS proposed an alternative available only to MSSP participants that would allow MSSP participants to satisfy the criterion if the ACO holds APM Entities accountable for their ECs' use of CEHRT by applying a financial penalty or reward based on the degree of CEHRT use. Now, CMS proposes to modify the existing MSSP EHR measure to align with QPP by assessing the ACO on the degree of CEHRT use by all providers and suppliers designated as ECs under the QPP proposed rule that are participating in the ACO. This represents a change from the current EHR measure, which looks more narrowly at the degree of CEHRT use by primary care physicians participating in the ACO. This modified criterion would be considered a pay-for-reporting measure for 2017 and 2018, but would change to a pay-for-performance measure beginning in 2019. CMS is also considering a variety of approaches regarding the treatment of the EHR measure under MSSP to further enhance the importance of the measure and improve alignment with QPP.[10]

ASSIGNMENT BASED ON BENEFICIARY PREFERENCES

The Proposed Rule would also allow individuals to voluntarily designate an ACO professional as responsible for their overall care (referred to by CMS as the beneficiary's "main doctor") for purposes of assignment to an ACO. This represents a significant change from the current MSSP, which does not allow for voluntary assignment and otherwise makes assignments under a system that analyzes the beneficiary's utilization of primary care services rendered by physicians participating in the ACO.

In particular, CMS would implement an "automated approach" (through a system such as MyMedicare.gov) to determine which provider a Medicare fee-for-service beneficiary believes is their main doctor based on information collected in an automatic and standardized manner from beneficiaries, rather than requiring ACOs and ACO participants to obtain this information and communicate it to CMS. Under this approach, beneficiaries would be able to change their main doctor at any time.[11]

CMS would incorporate voluntary alignment for Tracks 1 and 2 on a quarterly basis, meaning that beneficiaries who voluntarily align with a provider participating in a Track 1 or 2 ACO would be reflected in the ACO's next preliminary prospective or final assignment list. Conversely, if a beneficiary voluntarily aligns with a provider or supplier not participating in an ACO, the beneficiary would not be eligible for assignment to an ACO, even if the beneficiary would have otherwise been assigned to an ACO under the current claims-based assignment approach. For Track 3 ACOs, beneficiaries would be prospectively assigned to the ACO based on their designation prior to the start of the applicable performance year. These beneficiaries would remain assigned to the Track 3 ACO until the end of the benchmark or performance year, even if they later designate a practitioner outside the ACO as their main doctor, to ensure a stable beneficiary population.[12]

CMS proposes making this system available in early 2017, for the 2018 performance year. However, if this system is not ready by that time, CMS would implement a "manual" voluntary alignment process, available for Track 3 ACOs only, for the 2018 performance year.[13] CMS also notes that ACOs and others should not be permitted to offer gifts or other inducements to beneficiaries, nor should they be allowed to withhold or threaten to withhold services, for purposes of coercing or influencing beneficiaries' voluntary alignment decisions. That said, CMS indicates it would not prohibit an ACO or an ACO professional from providing a beneficiary with "accurate

descriptive information about the potential patient care benefits of designating an ACO professional as responsible for the beneficiary's overall care."[14]

Under either approach, beginning in performance year 2018, beneficiaries who have voluntarily aligned with an ACO will be added to the ACO's list of assigned beneficiaries under the following conditions:

- The beneficiary has at least one primary care service with a physician who is an ACO professional and is either a primary care physician or has one of the primary specialty designations included in § 425.402(c).[15]
- The beneficiary meets the current assignment eligibility criteria and is not excluded by the criteria at § 425.401.[16]
- The beneficiary designates an ACO professional who is a primary care physician, a physician with a specialty designation included at § 425.402(c), or a nurse practitioner, physician assistant, or clinical nurse specialist as responsible for their overall care.
- The designation is made in the form and manner and by a deadline determined by CMS.

SNF 3-DAY WAIVER RULE

Finally, the Proposed Rule would change the existing SNF 3-day waiver rule under MSSP. Currently, the Medicare SNF benefit is for beneficiaries who require a short-term intensive stay in a SNF, but beneficiaries must have a prior inpatient hospital stay of no fewer than three consecutive days in order to be eligible for Medicare coverage. CMS previously provided Track 3 ACOs with flexibility by allowing them to apply for a waiver of the SNF 3-day rule for their prospectively assigned beneficiaries when they are admitted to certain SNF affiliates with whom the ACO has entered into SNF affiliate agreements. In the Proposed Rule, CMS expresses concern about financial risk to beneficiaries due to a potential lag in communication from the time when a beneficiary may no longer qualify for a waiver of the 3-day rule and when the ACO can reasonably notify the beneficiary of that fact. To address this issue, CMS proposes introducing a grace period that would allow a beneficiary to continue to receive covered SNF services under the SNF waiver for up to 90 days after CMS delivers the quarterly beneficiary exclusion list to an ACO that removes the beneficiary from the ACO.[17]

Accordingly, CMS would make payments for SNF services furnished to such beneficiaries if the following conditions are met:

- The beneficiary was prospectively assigned to a waiver-approved ACO at the beginning of the performance year but was excluded in the most recent quarterly exclusion list.
- The SNF affiliate furnishes services to a beneficiary admitted within 90 days following the date that CMS delivers the quarterly exclusion list to the ACO.
- CMS would have otherwise made payment to the SNF affiliate for the services under the SNF 3-day rule waiver, but for the beneficiary's exclusion from the waiver-approved ACO's prospective assignment list.[18]

CONCLUSIONS

This Proposed Rule represents one step toward harmonizing MSSP with the significant physician reimbursement changes that MACRA is heralding, and it is unlikely to be the last. Track 1 ACOs are currently the largest cohort within MSSP, and their status as APMs — but ***not*** Advanced APMs — will generate a number of questions and interactions between the MACRA and MSSP rules. ACOs may also face significant impacts from the introduction of the voluntary beneficiary alignment provision. This provision could help reduce an ACO's uncertainty regarding what population base it is serving. However, in areas where multiple ACOs are serving the same markets, it could also serve as an area of increased competition, as providers vie for voluntary alignment from the same population base.

Notes:

[1] Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; etc., 81 Fed. Reg. 46,161 (July 15, 2016), https://www.gpo.gov/fdsys/pkg/FR-2016-07-15/pdf/2016-16097.pdf.

[2] More information about the Core Quality Measures Collaborative can be found at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/Core-Measures.html.

[3] In particular, the Merit-Based Incentive Payment System under the QPP consolidates the Physician Quality Reporting System ("PQRS"), the Value Modifier, and the Medicare Electronic Health Record ("EHR") incentive program.

[4] For example, the Proposed Rule would replace ACO-39 (Documentation of Current Medications in the Medical Record) with ACO-12 (Medication Reconciliation Post-Discharge), add ACO-44 (Use of Imaging Studies for Low Back Pain), and retire ACO-9 and ACO-10 (Ambulatory Sensitive Conditions Admission measures). *See* Table 36 at 81 Fed. Reg. 46,421 for a full list of MSSP quality measures, including CMS's proposed changes.

[5] 42 C.F.R. §425.500; *see* 81 Fed. Reg. 46,423.

[6] 81 Fed. Reg. 46,423.

[7] *Id.* at 46,474 (to be codified at 42 C.F.R. § 425.500).

[8] *Id.* at 46,426.

[9] *Id.* at 46,428.

[10] *Id.* at 46,429–31.

[11] *Id.* at 46,434.

[12] *Id.*

[13] *Id.* at 46,473 (to be codified at 42 C.F.R. § 425.402).

[14] *Id.* at 46,436.

[15] Current specialties listed in the regulations include cardiology, osteopathic manipulative medicine, neurology, obstetrics/gynecology, sports medicine, physical medicine and rehabilitation, psychiatry, geriatric psychiatry,

pulmonary disease, nephrology, endocrinology, multispecialty clinic or group practice, addiction medicine, hematology, hematology/oncology, preventive medicine, neuropsychiatry, medical oncology, and gynecology/oncology.

[16] Under 42 C.F.R. § 425.401(b), a beneficiary will be excluded if he or she meets any of the following criteria: (1) the beneficiary does not have at least one month of Part A and Part B enrollment and has any months of Part A only or Part B only enrollment; (2) the beneficiary has any months of Medicare group (private) health plan enrollment; and (3) the beneficiary does not live in the United States based on the most recent available data.

[17] 81 Fed. Reg. 46,439–41.

[18] *Id.* at 46,439.

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