HHS Is Embracing A Broader Vision Of Health Care

By **Michael Lampert, Cara Dermody, Samuel Perrone, Henry Lifton and Lauren Nikodemos** (February 21, 2019)

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In the last month, divisions of the U.S. Department of Health and Human Services have taken three separate actions that, while individually distinct, collectively reflect continuing interest in facilitating high-value care delivery that goes far beyond traditional models. The actions are:

On Jan. 18, 2019, the Center for Medicare and Medicaid Innovation announced an expansion to its Medicare Advantage value-based insurance design model, with wellness and health care planning as one component of the expansion.

On Jan. 29, 2019, HHS's Office of Inspector General issued an advisory opinion permitting a drug manufacturer to offer medication-adjacent technology to patients.

On Jan. 30, 2019, the Centers for Medicare & Medicaid Services issued Part II of its 2020 Advance Notice of Methodological Changes for Medicare Advantage Capitation Rates, Part C and Part D Payment Policies, and Draft Call Letter. In that letter, CMS expanded its interpretation of allowable nonmedical health benefits for certain populations.

Taken together, these developments suggest federal regulators are increasingly persuaded by the value of investing in items and services that go beyond conventional approaches to health care. This article summarizes the developments and considers their implications.

Expansion of Value-Based Insurance Design Model

History of CMMI's VBID Model

In 2017, CMMI launched the VBID innovation model to test how MA plans in seven states could use health plan design elements (e.g., supplemental benefits, disease management, reduced cost sharing) to encourage enrollees with specified chronic conditions to use high value clinical services or providers to improve quality of care while reducing costs. CMS allowed MA plans to test VBID interventions for the following diseases: diabetes, congestive heart failure, chronic obstructive pulmonary disease, past stroke, hypertension, coronary artery disease, mood disorders and combinations of these categories. Only coordinated care plans, including health maintenance organizations and local preferred provider organizations, were allowed to participate in the VBID model.

CMS subsequently expanded the program to three additional states in 2018, and to 15 more states in 2019. The 2019 expansion also allowed participants to propose a methodology that either (1) identified enrollees with different chronic conditions than those previously established by CMS or (2) revised the existing approved CMS chronic condition category to focus on a broader or smaller subset of the existing chronic condition. The Bipartisan Budget Act of 2018 mandated that CMS expand the VBID model to all 50 states and to other U.S. territories by 2020.

2020 Fifty-State Expansion

On Jan. 18, 2019, CMMI announced that, in 2020, CMS will expand health plan innovation under the VBID model to eligible MA health plans in all states and other U.S. territories.[1] In addition to currently eligible plan types, regional preferred provider organizations and all special needs plan, or SNP, types — chronic condition SNPs, dual eligible SNPs and institutional SNPs — are allowed to apply to the VBID model for 2020.

CMS will allow participating plans to test four additional service delivery model components. The first three components are optional. The final component — wellness and health care planning — is mandatory for VBID model participation.

- Value-based insurance design by condition, socioeconomic status or both. The first component will allow value-based insurance design by condition, socioeconomic status or both. This delivery model is a nonuniform benefit design to provide reduced cost sharing or additional supplemental benefits for enrollees based on condition or certain socioeconomic status (i.e., low-income subsidy eligibility or dual-eligible status).

- Medicare Advantage and Part D rewards and incentives programs. The second component is rewards and incentives, which CMS defines as meaningful and focused Medicare Advantage and Part D rewards and incentives programs.

- Telehealth networks. Under the third component, telehealth networks will provide increased access to telehealth services by allowing plans to propose using access to telehealth services instead of in-person visits, as long as an in-person option remains, to meet certain requirements for the provider network.

- Wellness and health care planning. The wellness and health care planning, or WHP, component mandates that participating organizations provide timely, coordinated approaches to wellness and health care planning, including advance care planning, such as advance directives. This is a required component for all VBID participating MA plans. Through the VBID model, CMS will evaluate the impact on quality and cost of best practices for performing WHP in the MA patient population.

According to CMS's actuarial guidance supporting the call letter,[2] MA plans participating in the model will be required to offer health care planning to beneficiaries, working with their provider network, by the earlier of (1) the second visit with the patient that occurs during the applicable model year or (2) the annual wellness visit or any health risk assessment.

CMMI will release additional information and guidance on the expanded VBID model in the coming months.[3]

CMMI's founding purpose is to "test innovative payment and service delivery models to reduce program expenditures ... while preserving or enhancing the quality of care furnished to individuals."[4] Expansion of the VBID model broadly demonstrates a strong push for MA plans to engage with enrollees in ways that could help enrollees, as patients, to access care more readily, and to incentivize individuals to participate more fully in their own care. At a high level, and similar to other CMS initiatives, the VBID model can be seen as an effort to change care delivery through payment structures — and to do so in a way that encourages patients to use new tools to access care and health improvement.

Significance of New OIG Advisory Opinion for Drug and Device Manufacturers Interested in Offering Nonmedical Items

In its Jan. 29, 2019, advisory opinion,[5] No. 19-02, the OIG approved a pharmaceutical manufacturer's proposal to loan limited-functionality smartphones to financially needy patients to improve medication adherence.[6] In brief, the opinion concluded that the promotes access to care exception to the beneficiary inducements civil monetary penalty, which was enacted as part of the Affordable Care Act and which the OIG subsequently adopted into regulation, protects the proposed arrangement, and that the proposed arrangement would not merit enforcement under the Anti-Kickback Statute.

The advisory opinion addresses a pharmaceutical manufacturer that developed a digital version of an antipsychotic medication that can be administered in the form of a tablet embedded with an ingestible sensor. The sensor transmits a signal to a wearable patch on the patient's abdomen, which records that the patient ingested the drug and tracks other indicators of the patient's reactivity. The patch then transmits the collected information to an application on the patient's smartphone, which then transmits the information to a cloud-based server through which the patient's health care providers and caregivers can access the information.

The pharmaceutical manufacturer proposed to loan smartphones to patients for the duration of their drug therapy, as long as the patients met certain requirements, such as having a prescription for the drug for on-label use, having an annual income below a specific percentage of the federal poverty level, and not already having a device capable of running the application. In addition, the manufacturer proposed a number of protections to reduce the risk of abuse, such as loaning only refurbished, older model iPhones or Androids, limiting each device's functionality, and limiting the duration of time that each device may be loaned to a patient.

The OIG concluded that the application alone would not necessarily have independent value apart from the medication, and therefore would not constitute remuneration under the AKS or the beneficiary inducements CMP. That alone is significant, and worthy of note for innovators developing enhancements to traditional care. The OIG did, however, believe that the loaned telephones themselves, which would come with telephone service, would be viewed as remuneration that may influence a patient to select a particular prescriber or pharmacy and would therefore implicate the beneficiary inducements CMP.

However, OIG determined that the proposed arrangement would satisfy the criteria of the promotes access to care exception to the beneficiary inducements CMP, given that (1) loaning the device would improve a beneficiary's ability to obtain items and services payable by Medicare or Medicaid, and (2) the safeguards around the arrangement would result in

the remuneration posing a low risk of harm.[7] OIG applied the same analysis when concluding that it would not seek sanctions under the AKS, concluding that the safeguards would prevent the loaned phone from influencing a beneficiary in violation of the AKS.[8]

The program that OIG considered in the advisory opinion was narrow in several regards. However, as one of the few advisory opinions to determine that the promotes access to care exception would protect a proposed arrangement, and the first for the pharmaceutical market, the advisory opinion is significant. It also is significant that the OIG repeated the requestor's assertion that lack of medication adherence results in higher utilization of health care services and increased costs to the health care system. Although OIG did not apply that consideration to its legal analysis, the OIG did note that the arrangement "could increase patient safety and quality of care by enabling the patient to use a drug that would track adherence and communicate that data back to the prescriber."

Moreover, the OIG stated that the smartphone would improve a qualifying beneficiary's ability to access the full scope of benefits of the drug. This suggests OIG's willingness to apply the promotes access to care exception not only to improve a patient's ability to obtain care itself, but also to improve a patient's ability to obtain the maximum benefit possible from care — i.e., to enhance a patient's care delivery and experience. That is generally broadening the application of this exception.

Developments in Medicare Advantage Plans Create Opportunities to Offer Nonmedical Benefits

Expansion of Primarily Health Related Supplemental Benefits in 2019

In its Advance Notice of Methodological Changes for Calendar Year 2019 for MA Capitation Rates, Part C and Part D Payment Policies and 2019 draft call letter,[9] CMS expanded its interpretation of a "health care benefit" that an MA plan may offer as a supplemental benefit.[10] The Social Security Act permits MA plans to offer supplemental benefits to enrollees if the supplemental benefits are health care benefits. CMS has historically interpreted Section 1852(a)(3) of the Social Security Act as requiring a supplemental benefit (1) to not be covered by original Medicare, (2) to be primarily health related and (3) to require the MA plan to incur a nonzero direct medical cost.

Until last year, CMS interpreted "primarily health related" to mean that the primary purpose of the item or service is to prevent, cure or diminish an illness or injury. For 2019, however, CMS expanded its definition of "primarily health related" to embody items or services used to "diagnose, prevent, or treat an illness or injury, compensate for physical impairments, act to ameliorate the functional/psychological impact of injuries or health conditions, or reduce avoidable emergency and healthcare utilization."

When describing its decision to expand the interpretation of the term "primarily health related," CMS pointed to research demonstrating the value of certain items and services, such as fall prevention devices, in improving health and reducing health care utilization. In so doing, CMS suggested that its interest in transcending the usual boundaries of health benefits is in part a reaction to the established efficacy of nonmedical approaches in improving patient health outcomes.

Introduction of Nonprimarily Health Related Supplemental Benefits in 2020

On Jan. 30, 2019, CMS released part two of its 2020 Advance Notice and Draft Call Letter,[11] in which the agency — pursuant to the flexibility allowed by the Bipartisan

Budget Act of 2018 — proposes to expand further its definition of the supplemental benefits MA plans may offer.[12]

The Bipartisan Budget Act of 2018 amended Section 1852(a) of the Social Security Act to expand supplemental benefits that may be offered by MA plans to chronically ill enrollees. Section 1852(a)(3)(D)(iii) of the Social Security Act now defines a chronically ill enrollee as an individual who (1) has one or more co-morbid and medically complex chronic conditions that is life threatening or significantly limits the overall health or function of the enrollee, (2) has a high risk of hospitalization or other adverse health outcomes, and (3) requires intensive care coordination. As amended, Section 1852(a)(3)(D)(ii) does not require supplemental benefits to be primarily health related when they are provided to enrollees who meet the definition of chronically ill, as long as the benefit has a reasonable expectation of improving or maintaining the health or overall function of the enrollee as it relates to the chronic disease. CMS refers to these benefits as special supplemental benefits for the chronically ill.

For calendar year 2020, CMS will consider any enrollee with a condition identified as a chronic condition in section 20.1.2 of Chapter 16b of the Medicare Managed Care Manual to meet the statutory requirement of having "one or more co-morbid and medically complex chronic conditions that is life threatening or significantly limits the overall health or function of the enrollee."[13] In addition, CMS noted that MA organizations will have broad discretion in developing items and services they may propose as SSBCI if the item or service has a reasonable expectation of improving or maintaining the health or overall function of the enrollee as it relates to the chronic disease.

Examples of such items and services may include transportation for nonmedical needs, home-delivered meals beyond the current allowable basis, and food and produce. Those items and services may not, however, include capital or structural improvements to the home of the enrollee that could potentially increase property value (e.g., permanent ramps or widening hallways or doorways) in order to avoid anti-kickback implications or taxable improvements.

CMS is currently soliciting comments on whether MA plans should have the flexibility to determine what constitutes a chronic condition that meets the statutory standard and if CMS should consider alternative approaches to determining what meets this criterion. CMS is also soliciting comments on whether it should permit consideration of other factors, such as financial need, in determining what will be considered permissible SSBCI. CMS will accept comments through Friday, March 1, 2019, before publishing the final Rate Announcement and Call Letter by April 1, 2019.

Conclusion

While of course significant within their own domains, these three actions collectively reflect developing attention within HHS to innovative care models and arrangements that go beyond traditional care delivery — and, significantly, a measure of regulatory flexibility to support that innovation.

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[1] CMS Announces New Model to Lower Drug Prices in Medicare Part D and Transformative Updates to Existing Model for Medicare Advantage (Jan. 18, 2019), available here.

[2] https://innovation.cms.gov/Files/x/vbid-actuarialguidance2020.pdf

[3] VBID model - CY2020 Application Actuarial Guidance, available here.

[4] 42 U.S.C. § 1315a(a)(1).

[5] https://oig.hhs.gov/fraud/docs/advisoryopinions/2019/AdvOpn19-02.pdf

[6] Advisory Opinion No. 19-02 (Jan. 29, 2019), available here.

[7] Section 1128A(a)(5) of the Social Security Act contains the Beneficiary Inducements CMP, which provides for the imposition of civil monetary penalties against any person who offers or transfers remuneration to a Medicare or State health care program beneficiary that the benefactor knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of any item or service for which payment may be made by Medicare or a State health care program. Section 1128A(i)(6) of the Act defines remuneration for purposes of the Beneficiary Inducements CMP as including "transfers of items or services for free or for other than fair market value." However, Section 1128A(i)(6)(F) of the Act provides that the CMP does not apply to "remuneration which promotes access to care and poses a low risk of harm to patients and Federal health care programs" (the "Promotes Access to Care Exception").

[8] The AKS, which is located at Section 1128B(b) of the Act, prohibits the knowing and willful solicitation, receipt, offer or payment of any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, in return for either referrals of federal health care program patients or arranging, recommending, leasing or ordering any item or service reimbursed by a federal health care program.

[9] https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2019Part2.pdf

[10] Advance Notice of Methodological Changes for Calendar Year (CY) 2019 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2019 draft Call Letter (Feb. 1, 2018), available here.

[11] https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2020Part2.pdf

[12] Advance Notice of Methodological Changes for Calendar Year (CY) 2020 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2020 Draft Call Letter (Jan. 30, 2019), available here.

[13] Section 20.1.2 of Chapter 16b of the Medicare Managed Care Manual, available here, lists these conditions: chronic alcohol and other drug dependence; autoimmune disorders limited to polyarteritis nodosa, polymyalgia rheumatica, polymyositis, rheumatoid arthritis, and systemic lupus erythematosus; cancer, excluding pre-cancer conditions or in-situ

status; cardiovascular disorders limited to cardiac arrhythmias, coronary artery disease, peripheral vascular disease, and chronic venous thromboembolic disorder; chronic heart failure; dementia; diabetes mellitus; end-stage liver disease; end-stage renal disease requiring dialysis; severe hematologic disorders limited to aplastic anemia, hemophilia, immune thrombocytopenic purpura, myelodysplatic syndrome, sickle-cell disease (excluding sickle-cell trait), and chronic venous thromboembolic disorder; HIV/AIDS; chronic lung disorders limited to asthma, chronic bronchitis, emphysema, pulmonary fibrosis, and pulmonary hypertension; chronic and disabling mental health conditions limited to bipolar disorders, major depressive disorders, paranoid disorder, schizophrenia, and schizoaffective disorder; neurologic disorders limited to amyotrophic lateral sclerosis, epilepsy, extensive paralysis (i.e., hemiplegia, quadriplegia, paraplegia, monoplegia), Huntington's disease, multiple sclerosis, Parkinson's disease, polyneuropathy, spinal stenosis, and stroke-related neurologic deficit; and stroke.