CENTER for HEALTH LAW and POLICY INNOVATION
HARVARD LAW SCHOOL

On November 26, 2024, the Centers for Medicare & Medicaid Services (CMS) announced a proposed rule for Medicare Part C and D ("Notice of Proposed Rulemaking" or "NPRM"). The NPRM lays out several noteworthy proposals for plan contract year 2026 that have the potential to impact Food is Medicine. We are happy to chat about any and all of these policies over the coming months. Public comments on the NPRM are due on **January 27, 2025.**

Summary of Noteworthy Provisions:

Medicare Part D (prescription drug) coverage for GLP-1 and other "anti-obesity medications"

- Discussion of changes begins at III.A
- Proposal: Historically, Medicare Part D drug coverage has largely excluded drugs used for weight loss or chronic weight management. (We say largely because drugs could only be included as a supplemental benefit.) The NPRM would reinterpret the statute to provide coverage when used for weight loss or chronic weight management for the treatment of obesity. The change would *not* extend to overweight, even with a weight-related comorbidity.
- Highlights from the NPRM:
    - CMS is not proposing to define obesity.
    - Among other facets, CMS solicits comments on the dividing line that it proposes to establish between obesity and overweight.
    - CMS references the National Strategy and Medicare/Medicaid opportunities promoted therein to support beneficiary access to nutrition-related services and supports as part of its rationale. The Agency is adding "another tool" to build on the National Strategy.

Codifying standards for use of debit cards

- Discussion of changes begins at III.F
- Proposal: CMS proposes to clarify and codify what it says are existing guardrails for supplemental benefits administered via debit card. For example, CMS proposes to build on existing guidance that cards must be "exclusively linked" to the covered item or service by codifying a requirement that cards are "electronically linked" to the benefit. CMS also proposes to require (i) instructions for use and customer service support, (ii) that plan benefit disclosures explicitly mention debit cards where benefits are administered via debit cards, (iii) marketing limits, and (iv) an alternative process for reimbursement where use of the debit card is infeasible.
- Highlights from the NPRM:
    - CMS remains concerned about the use of debit cards, including that they will be used to purchase other goods or services and that enrollees will not be able to access the benefit

- CMS "strongly encourage[s] plans to partner with community-based providers or other local, smaller businesses when offering supplemental benefits, particularly regarding food and produce benefits that may be offered to chronically ill enrollees under SSBCI regulations at § 422.102(f). We believe that encouraging plans to contract with community-based providers will improve enrollee access to benefits. With covered benefits available in their communities, enrollees will be able to more readily and easily obtain and use covered benefits and thus have the potential to improve their overall health."
- In its commentary around the proposals, CMS offers a non-exhaustive list of over-the-counter items that are "permissible primarily health-related supplemental benefits." Included in the list are energy protein bars and power drinks, nutritional drinks/shakes, vitamins and minerals, and herbal supplements. The agency solicits comments on other items that should be included in the list.

Clarifications regarding SSBCI eligibility and non-qualifying items/services

- Discussion of changes begins at III.G and III.H
- Proposal:
  - Only certain individuals are eligible for SSBCI: "chronically ill enrollees." In statute, this term has a three-part definition. The individual must have: (i) one or more comorbid and medically complex chronic conditions that is life-threatening or significantly limits the overall health or function of the enrollee; (ii) a high risk of hospitalization or other adverse health outcomes; and (iii) require intensive care coordination. CMS wants to amend SSBCI eligibility language to clarify and emphasize that presence of a chronic condition cannot be the sole basis for qualifying someone as a "chronically ill enrollee."
  - CMS also proposes a list of items and services that are ineligible for coverage as SSBCI. Included in the list is "broad membership-type programs inclusive of multiple unrelated services and discounts." CMS identifies Costco and Amazon Prime as examples of prohibited memberships. Plans would still be able to contract with the underlying retailers to offer covered benefits through, for example, a restricted debit card.
- Highlights from the NPRM:
  - CMS is concerned that plans have been conducting inconsistent and subjective eligibility determinations.
  - CMS offers health risk assessments and claims reviews as two "objective processes" that can be used to confirm eligibility.
  - In its discussion of items and services ineligible for coverage as SSBCI, CMS reaffirms its 2019 guidance identifying food and produce to assist chronically ill enrollees in meeting nutritional needs as SSBCI.

Promoting community-based services

- Discussion of changes begins at III.K
- Proposal:
  - The NPRM contains a series of proposals aimed at boosting transparency about non-traditional providers. Of particular note, CMS would require plans to identify, within the provider directory, which entities meet the proposed definition of a CBO. Additionally, plans would have to identify in-home or at-home supplemental benefit providers either through a subset list within the provider directory or through a separate list. The proposed definition for CBO is "public or private not-for-profit entities that provide specific services to the community or targeted populations in the community to address the health and social needs of those populations."
- Highlights from the NPRM:
  - As part of its rationale, CMS explains that because many supplemental benefits include interaction with an enrollee at the enrollee's home (e.g., meal delivery), a greater safety risk exists for enrollees who use these services. "This is particularly of concern when the enrollee may not have information about who may have access to their home, personally identifiable information (PII), or protected health information (PHI)."
  - Another rationale for the change is that enrollees are not readily able to tell from a provider directory which contracted providers are local CBOs. With more information, enrollees can choose to receive their benefit from CBOs "that are more familiar with their community, can better coordinate supportive services, and further address their community needs."
  - CMS again "strongly encourages plans to do business with organizations deeply rooted within the community they serve and may be best suited to serve." The Agency also mentions the importance of investing in local economies.
  - CMS potentially nods at covering food and nutrition supports as general supplemental benefits. "[A] plan could elect to offer a meal or food and produce supplemental benefit (so long as the benefit meets the requirements of § 422.100(c)(2) and other requirements for supplemental benefits) and pay a CBO for furnishing the covered benefit."

Impacts on Medicaid policy

- "Anti-obesity medications" have historically been an optional benefit in state Medicaid programs. The proposed reinterpretation summarized above would mean that, when used for weight loss or chronic weight management for the treatment of obesity, drugs would have to be covered.

Logistics

- The NPRM has not yet been officially published in the *Federal Register*; it is possible that some language may change between now and then.
- Comments are due January 27.