NATIONAL COALITION ON HEALTH CARE

Working Together for an Affordable Future

January 16, 2018

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4182-P
P.O. Box 8013
Baltimore, MD 21244-8016

Submitted electronically to www.regulations.gov
Re: CMS-4182-P

Dear Administrator Verma:

The National Coalition on Health Care (NCHC) appreciates this opportunity to comment on the proposed changes to the Medicare Advantage (MA) and the Medicare Prescription Drug Benefit programs (CMS-4182-P).

NCHC is the nation's largest, most broadly representative nonpartisan alliance of organizations focused on health care. The Coalition is committed to advancing—through research and analysis, education, outreach, and informed advocacy—an affordable, high-value health care system for patients and consumers, for employers and other payers, and for taxpayers. Our members and supporters include more than 80 of America's leading associations of health care providers, businesses and unions, consumer and patient advocacy groups, pension and health funds, religious denominations, and health plans.

In general, NCHC is encouraged that CMS is actively pursuing improvements to the Medicare Advantage program. We are particularly pleased that the agency is using the rulemaking process to engage the full range of stakeholder and public perspectives on its proposals. Nearly one in three Medicare beneficiaries exercise their option to receive Medicare benefits through MA Plans. In addition to providing important coverage choices, a well-functioning MA program has the potential to advance delivery, payment, and benefit reforms that will improve health care affordability overall.

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Our specific comments on the proposed rule are detailed below.

Implementation of the Comprehensive Addiction and Recovery Act of 2016 (CARA)

NCHC supports the provision of the Comprehensive Addiction and Recovery Act of 2016 that would limit opioid prescriptions to specific prescribers and pharmacies for at-risk beneficiaries. We are encouraged that CMS is promulgating regulations to implement these important provisions of law.

Flexibility in Medicare Advantage Uniformity Requirements (§422.100(d))

Proposal: CMS has now determined that statute permits MA organizations to reduce cost sharing for certain covered benefits; offer tailored, health-related supplemental benefits; and offer lower deductibles for enrollees that meet specific medical criteria, provided that similarly situated enrollees (that is, all enrollees who meet the identified criteria) are treated the same. Reviews of plan designs could still serve to prevent cost-sharing from discriminating against high-cost beneficiaries. Also, CMS notes that the new flexibility would still prohibit an MA plan from denying, limiting, or conditioning the coverage or provision of a service or benefit based on health status-related factors.

Discussion: NCHC supports allowing plans to reduce cost-sharing for certain benefits, tailor supplemental benefits, and vary deductibles for patients with specific medical criteria. Experience with such value-based insurance design (VBID) in employer plans shows that it can increase use of high-value treatments and providers in ways that lower overall costs and disease burden over time.

Reduced cost-sharing for highly effective preventive services and chronic care therapies addresses financial barriers that can prevent people from getting needed care and improves adherence to high-value treatments. This in turn can prevent costly complications and yield net savings.

There is already substantial evidence on the powerful benefits of VBID:

- Private employers like Pitney Bowes have found significant savings through reduced cost-sharing for essential diabetes treatments.
- Oregon's Public Employees' Benefit Board and the Oregon Educators Benefit Board's extensive VBID program improved HEDIS scores, increased use of preventive services, and provided substantial savings.
- The U.S. Department of Health & Human Services prominently features VBID in its National Quality Strategy.
- The University of Michigan Center for Value-Based Insurance Design tracks case studies and more at http://www.sph.umich.edu/vbidcenter.

This evidence provides more than a sufficient basis to incorporate VBID throughout the Medicare Advantage program even as the Medicare Advantage-specific VBID demonstration program progresses.

However, the proposed rule either lacks clarity or may not explicitly permit several important flexibilities, such as using relevant non-medical criteria (i.e. functional status, homelessness, income, living alone) to target tailored benefits, the ability to completely eliminate rather than reduce cost-sharing, and the ability to reduce cost-sharing for a subset of high-quality network providers.

Recommendation: We support the proposal and encourage CMS to finalize it. At the same time, CMS should provide additional clarification either in the final rule or in subsequent guidance. Specifically, NCHC encourages the agency to permit plan sponsors to

- Use non-medical factors as a criterion for a tailored benefits, such as living alone, low income status, or difficulties with ADLs or IADLs;

- Allow plans to eliminate the plan level deductible and cost-sharing (make $0), not just reduce them to a non-zero level; and

- Reduce cost-sharing only for a subset of high-quality network providers, as long as all members with the specified medical conditions receive the same lower cost-sharing for using these providers.

Finally, even as CMS implements VBID approaches in MA, we note that Advanced APM models bear accountability for clinical outcomes and beneficiary costs – albeit in a different manner than MA plans. NCHC encourages you to explore the ways in which ACOs and provider organizations participating in the Medicare Shared Savings Program and CMMI demonstrations might apply the principles of VBID and flexible benefits reflected in this proposed rule.

Meaningful Differences in MA Bid Submission and Bid Review (§§422.254 and 422.256)

Proposal: CMS proposes to eliminate the meaningful difference requirement for MA organizations (§§422.254(a)(4) and 422.256(b)(4) beginning in CY 2019.

Discussion: NCHC's member organizations have a broad range of positions with respect to meaningful difference requirements. However, NCHC does note that this proposal to add flexibility for plans could add complexity for beneficiaries. Currently, on average, beneficiaries have a choice of 21 MA plans. In 206 counties, beneficiaries chose among more than 30 plans for the 2018 plan year.[1]

[1] Jacobson, G, Damico, A., and Neuman, T. Medicare Advantage 2018 Data Spotlight: First Look. Available at: https://www.kff.org/medicare/issue-brief/medicare-advantage-2018-data-spotlight-first-look/

In proposing these changes, CMS has expressed confidence that improvements in the Plan Finder, the only tool for plan comparison, will help beneficiaries to navigate the new complexities. We appreciate that CMS is developing Plan Finder enhancements. Beneficiary choice is meaningless if beneficiaries do not have the tools to reasonably exercise that choice.

Recommendation: In the event that CMS proceeds to implement this proposal, such implementation must be matched with an aggressive effort to ensure that beneficiaries have adequate tools to evaluate and compare their choices. The Annual Notice of Change (ANOC), where practicable, should be used to inform beneficiaries about providers' exits from a plan network, the plan formulary changes, and where utilization management tools will be newly applied. The Plan Finder should include information about provider networks, office visit and service copays, and coinsurances.

Medical Loss Ratio

Proposal: CMS proposes to allow anti-fraud activities and Medication Therapy Management (MTM) under the MLR standard for Medicare Part C/D plans.

Discussion: Both anti-fraud efforts and MTM programs help to improve quality, and should count, as other quality efforts already do. Fraud, for example, can include claims for needed care not delivered and the delivery of unnecessary care, both of which have potential to cause physical as well as financial harm to enrollees. MTM programs focus on appropriate drug utilization among patients with complex care needs, for whom inappropriate utilization can be common and especially problematic.

Recommendation: We support adding anti-fraud efforts and Medication Therapy Management (MTM) program costs to what counts as medical spending for the medical loss ratio.

Star Ratings after Consolidation of Contracts

Proposal: CMS proposes a new set of rules for the calculation of Star Ratings for consolidated contracts. In most cases, the Star Ratings for the first and second years following the consolidation would be an enrollment-weighted mean of the scores at the measure level for all contracts (that is, consumed and surviving contracts). For the QBP rating for the first year following the consolidation, CMS proposes to use the enrollment-weighted mean of the QBP rating of the surviving and consumed contracts (which would be the overall or summary rating depending on the plan type) rather than averaging measure scores. In subsequent years after the consolidation, CMS would determine QBP status based on the consolidated entity's Star Ratings displayed on the Medicare Plan Finder (MPF).

Discussion: For Medicare Part C to deliver on its promise of competition and value, beneficiaries need an accurate and understandable sense of the quality of the choices available in the market. We, like the Medicare Payment Advisory Commission (MedPAC) and others, believe it is important to change current policy that lets plans apply a higher rating from a remaining contract to lower-rated plans in other states when issuers consolidate contracts.

We believe CMS' proposal in this regard is a constructive improvement compared to the status quo. However, it appears insufficient to fully assure quality transparency and choice of plans. MedPAC elaborated on this insufficiency in its recent response to this NPRM:

> "The averaging method would only give an accurate picture of quality in a given geographic area if the two or more contracts involved in a given consolidation shared exactly the same service area.
>
> In the current cycle of contract consolidations (the end of 2017), there were 17 contract consolidations in which a contract below 4 stars was consumed by a contract at or above 4 stars. In only one of the cases was there any overlap of service areas."

Hence, even with the proposed use of enrollment-weighted averages of scores among consolidating plans, some lower-rated parts of consolidated contracts would receive higher scores than they have earned.

Recommendation: We urge CMS to finalize the existing proposal while continuing to consider additional options.

Expedited Substitutions of Certain Generics and Other Midyear Formulary Changes (§§423.100, 423.120, and 423.128)

Proposal: CMS proposes to revise regulations to permit Part D sponsors to immediately remove or change the preferred or tiered cost-sharing of brand name drugs when the sponsor replaces the brand drug with (or adds to their formularies) therapeutically-equivalent newly-approved generics. CMS would permit these substitutions and changes to occur at any time without advance approval.

Discussion: NCHC believes that enhanced competition from generic drugs is a powerful tool to restrain costs and improve affordability. We greatly appreciate the additional formulary flexibility that CMS proposes to offer Part D sponsors.

Recommendation: NCHC supports CMS' proposal to permit midyear changes and to allow them to proceed without advance approval.

Treatment of Follow-on Biological Products as Generics for Non-LIS Catastrophic and LIS Cost Sharing (423.4)

Proposal: CMS proposes to revise the definition of generic drugs at §423.4 to include follow-on biological products approved under section 351(k) of the Public Health Service (PHS) Act solely for the purposes of non-LIS catastrophic and LIS cost-sharing.

Discussion: Currently, because biosimilar and interchangeable biological products do not meet CMS' definition of a generic drug, they are subject to the higher Part D maximum copayments for LIS beneficiaries and non-LIS enrollees in the catastrophic portion of the benefit. CMS' proposal would ensure that follow-on biological products will be more affordable for beneficiaries than more expensive reference biological products. It will thereby reduce costs to both Part D enrollees and the Part D program.

Recommendation: NCHC supports CMS' proposal and recommends finalizing as proposed.

Price Concessions to Drug Prices at Point of Sale

Request for Information: CMS is soliciting comment on requiring plan sponsors to provide a percentage of manufacturer rebates and pharmacy price concessions in the negotiated price at point of sale. Comments may inform future rulemaking.

Discussion: We are pleased to see CMS exploring ways to reduce cost barriers to needed prescription drugs in Medicare Part D and soliciting comment from the full range of stakeholders prior to proposing immediate regulatory change.

However, given the complex arrangements between and among plan sponsors, pharmacies, and manufacturers, careful consideration of the consequences of any possible change is needed. NCHC has identified at least three causes for concern with the contemplated policies.

1. *Cost-shifting, not cost-saving:* CMS' own analysis shows that reduced beneficiary burden at point of sale would generate increased costs elsewhere. Specifically, Table 10A indicates that point of sale manufacturer rebates would yield between $9.2 billion and $28.3 billion (a 4-11%increase) in beneficiary premium costs, and $27.3 and $82.1 billion in added cost to federal taxpayers (a 2-6% increase). According to Table 11, applying this requirement to pharmacy price concessions would similarly generate $5.7 billion in added premium costs and $16.6 billion in added taxpayer costs. In both cases, the added cost to beneficiaries and taxpayers combined exceed the reduction in out-of-pocket expenditures. This is not a cost-saving policy, it is a cost-shifting policy—with negative consequences for premium affordability and the Federal Treasury.

2. *Ignoring the root cause*: The root cause of the increasing unaffordability of prescription drugs lies in the underlying price of the drugs themselves, as reflected in unsustainable launch prices and ongoing price inflation of drugs already on the market. This proposal does not directly address the underlying lack of transparency, competition, and value in prescription drug market itself.

3. *Potentially encouraging drug price inflation*: NCHC is concerned that the reduction in manufacturer coverage gap responsibilities associated with the manufacturer rebate policy amounts to a Medicare-financed windfall to manufacturers. This windfall would serve to lessen what pressure does exist today for manufacturers to restrain list prices.

Recommendation: NCHC remains very interested in reducing cost barriers for needed care and addressing the underlying problems with pharmaceutical prices. But given the consequences described above, NCHC could not support any proposal to implement the specific options described in this RFI.

Should you or your team have any questions with respect to the issues addressed in this letter, please contact NCHC's Policy Director Larry McNeely at lmcneely@nchc.org or 202-638-7151.

Yours truly,

John Rother
President and CEO