January 5, 2024

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Ave., SW
Washington, D.C. 20201

SUBJECT: CMS-4205-P, Medicare Program; Contract Year 2025 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications (Vol 88, No. 219), Wednesday, November 15th

Dear Administrator Brooks-LaSure:

On behalf of more than 400 hospitals, CHA is providing comments on the Centers for Medicare & Medicaid Services' (CMS) proposed Contract Year 2025 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications (hereafter proposed rule).

Almost half of California's Medicare beneficiaries are enrolled in a Medicare Advantage (MA) plan. It is important for CMS to take steps to ensure that beneficiaries enrolled in MA have access to the same services as those in Medicare fee-for-service (FFS), can avail themselves of the same rights as those who remain in Medicare FFS, and that payments to MA plans are spent on activities that improve patient/member outcomes, not marketing and other administrative activities. The rule includes proposals that achieve these goals. In many instances these proposals could be improved.

There are concerns about the proposal to require beneficiary notification of unused supplemental payments. It is important to ensure that MA enrollees are making use of their supplemental benefits – particularly those benefits that support the management of chronic disease or address an unmet social determinant of health. However, requiring mid-year outreach to enrollees highlighting unused supplemental benefits is cumbersome and inefficient. The proposal will not have the intended effect of alerting MA enrollees about unused supplemental benefits due to data lags. There are better approaches that will achieve the same results at a lower administrative cost.

Finally, the rule is silent on CMS' role in MA plans' underpayment of 340B drugs provided by eligible hospitals to enrollees from 2018 – 2022. Given that MA plans in most circumstances did not benefit from

499 So. Capitol Street SW, Suite 410, Washington, DC 20003 ▪ Office: (202) 488-3740 ▪ FAX: (202) 488-4418

1215 K Street, Suite 700, Sacramento, CA 95814 ▪ Office: (916) 443-7401 ▪ www.calhospital.org

CMS' illegal policy, the agency should repay hospitals directly. Therefore, the statute does not prohibit CMS from taking this necessary action.

Detailed comments on the issues discussed above follow.

Medicare Advantage Underpayment for 340B Drugs

CHA is disappointed that CMS in the final 340B[1] remedy rule did not appropriately address Medicare Advantage Organizations (MAOs) underpayment to eligible hospitals for separately payable Medicare Part B drugs acquired under the 340B program. In that final rule, CMS stated comments from hospitals addressing this subject were out of scope as the proposed rule only applied to payments in the Outpatient Prospective Payment System (OPPS). However, the comments that follow are in scope as they are in response to proposed technical changes in the MA program for CY 2025.

As discussed below in detail, CHA is asking HHS to repay eligible hospitals for 340B drugs provided to MAO enrollees during CYs 2018 through 2022. If CMS does not directly repay hospitals on behalf of MAOs for 340B drugs provided to MAO enrollees, the agency's budget neutrality adjustment to the FFS market basket will unnecessarily reduce payments to MAO payments to hospitals. This payment reduction would inappropriately generate savings for the Part B trust fund – given that MA county level benchmarks are based on Medicare FFS spending. However, these savings would come at the expense of access to care for both Medicare and non-Medicare populations who are at risk of inequitable outcomes. In 2021, 47% of California's Medicare beneficiaries were enrolled in MAOs. Failing to fully rectify the underpayment as a result of HHS' illegal actions for 340B drugs provided to MA beneficiaries from 2018-2022 only compounds the financial stress this illegal policy imposed on safety net hospitals.

As HHS is aware, the reduction in payments for 340B drugs from 2018-2022 was done in a budget-neutral manner. The projected reduction in 340B payments was applied to the market basket update as a positive budget neutrality adjustment. For MAOs that are contracted with hospitals based on the OPPS PRICER, this would have simply shifted dollars from one OPPS category (e.g., separately payable 340B drugs) to another (e.g., items and services paid based on an ambulatory payment classification). As a result, in theory, MAOs should not have experienced an increase in capitated revenue nor a significant decrease in claims payments to hospitals. Given that MAOs contracting with hospitals based on the Medicare pricer did not profit from HHS' illegal policy, CHA asks that HHS directly pay eligible hospitals appropriately for separately payable 340B drugs provided to MA members from 2018-2022.

Specifically, HHS should use its prompt payment authorities under 42 U.S.C. 1395w-27(f) to directly pay eligible hospitals. Instead of requiring the plans to pay hospitals a lump sum settlement for 340B claims, HHS could pay hospitals directly without passing additional funds through to MAOs (or withholding funds without merit). CHA believes that 42 U.S.C. 1395w-27(f)(2) allows for this, as described below.

> *(2) Secretary's option to bypass noncomplying organization*[2]
> *In the case of a Medicare+Choice eligible organization which the Secretary determines, after notice and opportunity for a hearing, has failed to make payments of amounts in compliance with paragraph (1), the Secretary may provide for direct payment of the amounts owed to providers and*

[1] CMS–1793–F, Medicare Program; Hospital Outpatient Prospective Payment System: Remedy for the 340B-Acquired Drug Payment Policy for Calendar Years 2018–2022, (Vol 88, No 215), November 8, 2023.
[2] https://www.govinfo.gov/content/pkg/USCODE-2019-title42/pdf/USCODE-2019-title42-chap7-subchapXVIII-partC-sec1395w-27.pdf

> *suppliers (or, in the case of a Medicare+Choice private fee-for-service plan, amounts owed to the enrollees) for covered services and supplies furnished to individuals enrolled under this part under the contract. If the Secretary provides for the direct payments, the Secretary shall provide for an appropriate reduction in the amount of payments otherwise made to the organization under this part to reflect the amount of the Secretary's payments (and the Secretary's costs in making the payments)*[3].

To that end, 42 U.S.C. 1395w-27(f)(2) requires the Secretary to "provide for an appropriate reduction in the amount of payments otherwise made to the organization … to reflect the amount of the Secretary's payments." However, in this instance MAOs' "non-compliance" to make a direct payment is a result of the Secretary's illegal actions coupled with not providing sufficient funds for the MAO to make a lump sum settlement to eligible hospitals for separately payable Part B drugs acquired under the 340B program from 2018-2022 provided to MAO enrollees. Therefore, there is nothing for the Secretary to withhold from the MAOs in this instance.

Finally, CMS should instruct MAOs not to apply the .5% budget neutrality adjustment that begins in CY2026 to avoid inappropriately reducing payments to hospitals for care provided to MAO enrollees. California's hospitals continue to face unprecedented financial pressure resulting from the COVID-19 pandemic's impact on the labor market and the health care supply chain. From 2019 to 2022, costs per adjusted discharge rose 25%[4] (driven by increases in salary costs +22%, supply expenses +18%, and pharmaceuticals +19%). However, payment rates for Medicare and other governmental payers have failed to keep pace with input price inflation. Chronic underfunding by Medicare and other governmental payers contributed to the recent closure of one 340B hospital in California (Madera Community Hospital[5,6]), drove another into bankruptcy (Beverly Hospital[7]), and has forced others to eliminate financially unsustainable services to ensure the facilities can remain open. And, unfortunately, more hospital closures are anticipated. Kaufman Hall, a nationally renowned consulting firm, estimates 20% of California's hospitals are currently on the financial brink.

The financial challenges facing hospitals — which are recognized in the Medicare Payment Advisory Commission's (MedPAC) 2024 hospital payment update recommendations to Congress[8] and the 2025 draft recommendation[9] to Congress— threaten access to care for not just Medicare beneficiaries, but all members of the affected community. Following hospital or service line closures, patients are forced to travel farther distances for care in already overcrowded hospitals, resulting in negative outcomes. Research shows that rural hospital closures increase inpatient mortality by 8.7%, with Medicaid patients (including those who are dually eligible) and racial minorities bearing the brunt of negative outcomes — 11.3% and 12.6% increases in mortality, respectively. These are not abstract data points. Sadly, two individuals' deaths have already been attributed[10] to Madera Community Hospital's closing. CHA is concerned that if MAOs implement this unnecessary budget neutrality adjustment as a result of its inclusion in the Medicare FFS pricer, it will result in more hospital closures, the rationalization of

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[3] Emphasis added
[4] https://www.kaufmanhall.com/insights/research-report/california-hospital-financial-impact-report-april-2023-update
[5] https://calmatters.org/health/2023/01/hospital-closure/
[6] https://abc30.com/madera-commuity-hospital-remains-closed-emergency-services-residents/12922392/#:~:text=Ashraf.-,Madera%20Community%20Hospital%20closed%20its%20doors%20in%20December%20of%20last,Madera%20for%20over%20forty%20years.
[7] https://www.latimes.com/california/story/2023-04-20/beverly-hospital-in-montebello-files-for-bankruptcy-in-effort-to-avoid-closure
[8] https://www.medpac.gov/wp-content/uploads/2023/03/Mar23_MedPAC_Report_To_Congress_SEC.pdf
[9] https://www.medpac.gov/wp-content/uploads/2023/03/Hospital-Dec-2023-SEC.pdf
[10] https://www.fresnobee.com/news/local/article272712840.html

unsustainable service lines, and access issues for MAO enrollees, Medicare FFS beneficiaries, and others who rely on safety net hospitals for care.

Expanding Network Adequacy Requirements for Outpatient Behavioral Health

CMS proposes to create a new facility type (Outpatient Behavioral Health), for which CMS can set MA plan network adequacy standards. The range of behavioral health providers under this category include marriage and family therapists (MFTs) and mental health counselors (MHCs) (services rendered by these qualified professionals were established as a new statutory Medicare benefit category through separate rulemaking in 2023), as well as Opioid Treatment Program providers, Community Mental Health Centers, addiction medicine physicians, and other providers who furnish addiction medicine and behavioral health counseling or therapy services.

The proposal to add the new facility type "Outpatient Behavioral Health," and the providers associated with the category, to the list of those subject to MA network adequacy requirements is supported. The proposed additions will expand outpatient behavioral health and opioid treatment access to MA beneficiaries and bring the types of mental health providers available to MA members in line with those available to Medicare FFS beneficiaries. Under existing network adequacy requirements, studies have shown that narrow networks significantly limit MA beneficiary access to various specialties, with access to psychiatrists being the most restricted. As CMS expands the specialty types subject to network adequacy requirements, the agency is urged to conduct appropriate oversight to ensure that MA networks are not so narrow that patients are unable to access the care they need.

Additionally, CMS is asked to provide flexibility in how it counts providers towards meeting the network adequacy standards. There are several different licensure and certification pathways an individual may pursue in order to provide behavioral health and addiction treatment services to MAO beneficiaries. As CMS has noted, there are a number of different provider types who provide outpatient behavioral health and addiction treatment services, including psychiatrists, licensed clinical social workers (LCSWs), nurse practitioners and clinical psychologists, MFTs, MHCs, physician's assistants (PAs), nurse practitioners (NPs), clinical nurse specialists (CNSs), and addiction medicine physicians.

All the provider types listed above are licensed and/or certified to provide mental/behavioral health counseling or psychotherapy, as permitted under state law, and should be considered for purposes of meeting enrollees' behavioral health needs. By designating each type of practitioner as individual specialties to evaluate against provider-to-beneficiary ratios and time and distance standards, CMS is effectively dictating which types of practitioners must be used to meet enrollees' behavioral health needs, rather than allowing plans to tailor their network of behavioral health professionals to meet the needs of their patient population.

Further, the presence and prevalence of certain types of behavioral health professionals in certain parts of the country has much to do with the types and prevalence of behavioral health education and certification programs in those areas. For example, in some parts of the country it may be more common to see a clinical psychologist (with PhD level training) for therapy whereas in others it may be more common to see a master's prepared LCSW. Setting specific time and distance standards for clinical psychology and clinical social work does not take into account the varying prevalence of these and other behavioral health professionals at the county level across the country.

With this consideration in mind, CHA asks that CMS revise its proposal to add a single new behavioral health/psychotherapy/addiction treatment category, defined to include all the professionals who are licensed and/or certified under state law to provide adult psychotherapy, including psychiatrists, licensed clinical social workers (LCSWs), nurse practitioners and clinical psychologists, MFTs, MHCs, physician's assistants (PAs), nurse practitioners (NPs), clinical nurse specialists (CNSs), and addiction medicine physicians. This will permit MAOs to ensure appropriate access to behavioral health and addiction treatment services using the providers who will best meet their population's needs and will allow for the variation in prevalence of different types of professionals across the country.

CMS also proposes to add the Outpatient Behavioral Health facility type to the list of specialties that qualifies MA plans for a 10% network adequacy credit if their contracted network includes one or more telehealth providers of that specialty type. **This proposal is supported and the agency is urged to finalize it.**

Enhancing Enrollees Rights to Appeal an MA Plan's Decision to Terminate Coverage for Non-Hospital Provider Services

Beneficiaries enrolled in Traditional Medicare have the right to a fast-track appeal by an Independent Review Entity (IRE) – currently, conducted by Quality Improvement Organizations (QIOs) – when their covered skilled nursing facility (SNF), home health, or comprehensive outpatient rehabilitation facility services are being terminated. Under current regulations, MA enrollees do not have the same access to QIO review of a fast-track appeal as Traditional Medicare beneficiaries. To align the MA program process with that under Traditional Medicare, CMS proposes to require the IRE (i.e., the QIO), instead of the MA plan, to review untimely fast-track appeals of an MA plan's decision to terminate services in an HHA, CORF, or SNF.

In addition, CMS proposes to allow enrollees the right to appeal the decision to terminate services after leaving a SNF or otherwise ending covered care before the planned termination date. Currently, if an MA enrollee misses the deadline (stated in the Notice of Medicare Non-Coverage) to appeal or ends services from the provider before the termination date, the enrollee loses their right to the fast-track appeal. However, in the same circumstances, beneficiaries in Traditional Medicare maintain their right to appeal in a parallel fast-track appeal process in effect under Traditional Medicare. **CMS is urged to finalize policies that ensure MA enrollees and Traditional Medicare beneficiaries have access to the same appeal rights and coverage benefits. CMS should also ensure that these appeal rights apply when beneficiary or MA enrollee coverage is terminated in other post-acute care settings, including inpatient rehabilitation facilities and long-term care hospitals by modifying 42 CFR § 422.622 in the final rule as well.**

Mid-Year Notice of Unused Supplemental Benefits

The rule expresses concern that MAO enrollees are not taking full advantage of their supplemental benefits. Therefore, to address this issue CMS proposes beginning Jan. 1, 2026, MAOs would be required to provide a model notification to enrollees of supplemental benefits they have not yet accessed. Specifically, MAOs would need to mail a mid-year notice annually (during the period beginning on June 30 and ending on July 31 of the plan year) to each enrollee with information on each supplemental benefit available during the plan year that the enrollee has not begun to use.

While the intent of the proposal is well meaning, there is concern about the ability for MAOs to operationalize it in manner that achieves CMS' intended goal of increasing supplemental benefit utilization and improving MAO member outcomes. As CMS is aware, many of the supplemental benefits offered by MAOs are provided by third parties (e.g., Silver Sneakers). Therefore, if this proposal is finalized MAOs will need to aggregate utilization data from disparate vendors into a single database to generate member specific utilization reports. It will take time to clean and standardize this data. Given the need for this data cleaning there will be significant lags in the data which will likely result in a supplemental benefit utilization snapshot that includes only four months (or fewer) which decreases the utility of this tool. **A better approach in the final rule to achieving the goal of reminding MAO enrollees about their supplemental benefits is to require plans to send a mid-year notice reminding enrollees of all of their available benefits (regardless of whether they have been used) and providing a link to information on how to access them.**

Annual Equity Analysis of Utilization Management Policies and Procedures

The proposed rule states that "prior authorization policies and procedures may have a disproportionate impact on underserved populations and may delay or deny access to certain services." As such, CMS proposes additional requirements for MAOs to conduct an annual health equity analysis of their prior authorization (PA) and utilization management (UM) policies and procedures from a health equity perspective (using specified metrics) through their required Utilization Management Committee (UMC). The agency also proposes requiring that a member of the UMC have expertise in health equity and that the results of the annual health equity analysis be made publicly available on the MA plan's website.

CMS' acknowledgement of reports from hospitals and providers that UM practices, especially prior authorization (PA) can create access barriers to medically necessary care is most appreciated. These administrative barriers disproportionately affect historically underserved and marginalized MAO enrollees. **The rule's proposal that MAOs require UMCs include an individual with expertise in health equity, and conduct an annual health equity analysis of UM policies that is made publicly available is supported.**

The metrics proposed for the health equity analysis of UM policies and procedures are supported. The specific attention to rates of approved and denied PA requests, the timelines for these determinations, and need for/outcome of any PA appeals is a positive step in addressing access issues experienced by at risk beneficiaries. Data from California's hospitals finds that MA patients are 3.5 times more likely than those with commercial insurance to experience a discharge delay[11]. Further, 79% of responding hospitals report that delay and/or denial of prior authorization is the most significant issue causing discharge delays. Given these issues, CMS is encouraged to require MAOs to provide disaggregated data on access to medically necessary post-acute care which should include LTCHs, IRFs, SNFs, and HHAs. Further, to ensure that this information is useful to beneficiaries, the agency, policy makers, and other key stakeholders, it must be provided in a standardized format to allow for an apples-to-apples comparison. Therefore, CHA respectfully asks CMS to work with key stakeholders to create a standardized template that MA plans are to use when they make this information available.

[11] Survey of California Hospital Association Members, October 2023

For D-SNP PPOs, Limit Out-of-Network Cost Sharing

CMS proposes, beginning Jan. 1, 2026, to require D-SNP PPOs (both local and regional) to cap out-of-network cost sharing for professional services at the cost sharing limits for those services established at §422.100(f)(6) when furnished in network. The term "professional services" would have the meaning given in section 422.100(f)(6)(iii), which includes primary care services, physician specialist services, partial hospitalization services, and rehabilitation services.

CMS also proposes to require that cost sharing for out-of-network acute and psychiatric inpatient services be limited by the cost sharing caps under §422.100(f)(6) for in-network benefits. Thus, the cost sharing limit for a D-SNP PPO with a catastrophic limit set at the mandatory maximum out-of-pocket (MOOP) limit would not exceed 100% of estimated Medicare FFS cost sharing, including the projected Part A deductible and related Part B costs, for each length-of-stay in an out-of-network inpatient or psychiatric hospital. For catastrophic limits equivalent to the intermediate and lower MOOP amounts, higher cost sharing for out-of-network cost sharing for inpatient and psychiatric stays could be charged as described at §422.100(f)(6)(iv)(D)(2) and (3), respectively.

Most enrollees in D-SNP PPOs are protected from being billed for covered Medicare services by Medicare providers, including out-of-network providers, with state Medicaid agencies paying, or the provider foregoing the payment of, cost sharing. As a result, providers and hospitals frequently receive less than they would have received under Medicare FFS when the state Medicaid agencies limits payment of Medicare cost sharing. This runs counter to the statutory requirement under section 1852(a)(2)(A) of the Act that out-of-network providers and hospitals receive no less than the Medicare FFS amounts, including applicable cost sharing. CMS' thoughtful discussion of an issue that contributes to inadequate payment for out-of-network services provided to vulnerable dual eligible beneficiaries is much appreciated. **The agency is urged to finalize these proposals as they will ensure that providers, acute hospitals, and psychiatric hospitals providing services to out-of-network D-SNP PPO enrollees are paid no less than the Medicare FFS amount as required by statute.**

Reducing Threshold for Contract Limitation on D-SNP Look-Alikes

CMS expresses concern over the recent growth in non-SNP MA plans with a percentage of dually eligible enrollees between 50% and 80% of total enrollment. This increased growth suggests to the agency that MAOs are offering plans for dually eligible individuals but circumventing rules for D-SNPs. In response, the agency proposes to lower the D-SNP look-alike threshold to 70% for contract year 2025 and 60% for contract year 2026. **This proposal is strongly supported.**

Increasing the Percentage of Dually Eligible Managed Care Enrollees Who Receive Medicare and Medicaid Services from the Same Organization

The rule includes several proposals to increase the percentage of dually eligible individuals who are enrolled in integrated care plans that coordinate both Medicare and Medicaid benefits. These policies include:

- Replacing the current quarterly special enrollment period (SEP) with a one-time-per-month SEP for dually eligible individuals (and others enrolled in Part D low-income subsidy program) to elect a standalone Part D prescription drug plan

- Creating a new integrated care SEP to allow dually eligible individuals to elect an integrated Dual Eligible Special Needs Plan (D-SNP) monthly

If finalized, the rule would also limit enrollment in certain D-SNPs to those individuals who are also enrolled in an affiliated managed care organization and to limit the number of D-SNP plan benefit packages an MA plan or its parent company can offer in the same service area as an affiliated Medicaid managed care plan.

Conceptually, the enrollment of dually eligible individuals in MA and Medicaid managed care organization (MCO) plans provided by the same organization should increase opportunities to improve care coordination and beneficiary outcomes. However, actual experience with California's CalAIM program raises some concerns in light of the proposals in this rule. First, dually eligible beneficiaries must retain their ability to remain in Medicare FFS. It is of the utmost importance that the Medicare beneficiary's individual needs, circumstances and preferences are considered for each enrollment decision. Otherwise, there is concern that the Department of Health Care Services will take actions that, in essence, make D-SNP enrollment the default option for dually eligible individuals.

Second, many managed Medi-Cal plans have limited experience administering Medicare benefits. In these instances, they are not knowledgeable of Medicare's benefits and access standards. This creates unnecessary administrative barriers to medically necessary care for dually eligible enrollees that do not exist in Medicare FFS as these plans do not adjust their processes to reflect Medicare's statutory and regulatory requirements. As a result, beneficiaries enrolled in these plans may be unable to access services that they would have received under Traditional Medicare. Unfortunately, the scenario described above occurred frequently as part of coordinated care initiative (CCI)[12] undertaken by Medi-Cal Managed Care Plans (MCPs). These plans approached UM and PA for Medicare covered services using the same criteria and guidelines as Medi-Cal services. This is inappropriate and denies vulnerable dually eligible beneficiaries medically necessary services they are entitled to. Given the D-SNP population's limited resources and health challenges they are considerably more vulnerable than non-dual enrollees to adverse outcomes as a result of care denied because of inappropriate UM criteria.

Guardrails for Plan Compensation to Agents and Brokers

The proposed rule expresses concern that "financial incentives to agents and brokers can result in beneficiaries being steered to some MA plans over others based on excessive broker and agent compensation and other bonus arrangements – rather than recommending plans based on the prospective enrollee's best interests." Therefore, CMS proposes guardrails governing plan compensation for agents and brokers, including standardized compensation structures, with a stated goal of ensuring that compensation is used in a way that incentivizes individuals to enroll in the plan that best meets their health care needs. The rule proposes to redefine "compensation" to set a clear, fixed amount that agents and brokers can be paid regardless of the plan in which the beneficiary enrolls. The proposed rule also prohibits contract terms between MA plans and marketing middlemen that result in volume-based bonuses for enrollment into certain plans.

[12] The Coordinated Care Initiative (CCI) is a program that changed the way certain people in California get their health care and their long-term services and supports (LTSS). The CCI combines and coordinates certain health and other services, including mental health and other long-term services and supports (LTSS).

CMS's concerns about mis-aligned incentives for brokers and other agents are shared by hospitals. It is not uncommon for hospitals to encounter patients with significant medical conditions that are enrolled in products that are not well-suited to their ongoing clinical needs. Beyond ensuring that Medicare beneficiaries are enrolled in coverage that is best for them, this proposal will guarantee that more of the Medicare Trust Funds' limited resources are directed to improving patient outcomes. **Therefore, this proposal is supported.**

If you have any questions, please contact me at cmulvany@calhospital.org or (202) 270-2143, or Megan Howard, vice president of federal policy, at mhoward@calhospital.org or (202) 488-3742.

Sincerely,

/s/
Chad Mulvany
Vice President, Federal Policy