February 19, 2019

Alex Azar
Secretary
U.S. Department of Health and Human Services
200 Independence Ave. SW
Washington, DC 20201

Re: HHS Notice of Benefit and Payment Parameters for 2020 – Docket CMS-9926-P

Dear Secretary Azar:

Aimed Alliance is a 501(c)(3) non-profit organization that seeks to protect and enhance the rights of health care consumers and providers. Thank you for providing us with the opportunity to comment on Docket CMS-9926-P, *HHS Notice of Benefit and Payment Parameters for 2020.* This proposed rule would make significant changes to how marketplace and private health insurance plans operate, and these changes could negatively impact the ability of many patients to access health care treatment and services.

I. Mid-year Formulary Changes

The Center for Medicare and Medicaid Services ("CMS") proposes to allow issuers, beginning in 2020, to make mid-year formulary changes if a new generic medication is introduced to the market.[1] Health plans would be allowed to add the new generic medication to the formulary and remove the equivalent brand medication from the formulary or move it to a higher cost-sharing tier. This proposal is motivated by the desire to help plans save money if a new generic alternative is introduced onto the market.

We support adding new generic medications to the formulary, so patients have access to more affordable medications. However, CMS should not permit insurers to remove any medication from the formulary after the plan year has begun unless the medication is removed for safety reasons.

Removing a medication from a formulary in the middle of a plan year can result in nonmedical switching, a practice in which a stable patient is forced to switch from his or her current medication to an alternative based on a cost-driven formulary change. Nonmedical switching can have negative effects on patient health and outcomes.[2] While switching between a brand and a generic medication is typically not an issue, some generic medications have been known to affect patients differently than the brand drug, and some patients may experience adverse events.[3] For some conditions, the time wasted on the nonmedical switch could cause a patient's condition to worsen, which could be irreversible. For example, if a patient with multiple sclerosis is switched

[1] https://www.regulations.gov/document?D=CMS-2019-0006-0016
[2] http://www.keepmyrx.org/wp-content/uploads/2017/02/ProtectingPatientsFromNMS.pdf
[3] E.g., https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4106520/; https://www.webmd.com/add-adhd/news/20141114/two-generic-versions-of-adhd-drug-not-as-effective-fda

off of the disease modifying therapy that he or she is currently stable on and the new medication is not as effective as the old one at slowing the progression of the disease, the patient's multiple sclerosis could progress.[4] Disease progression in multiple sclerosis patients could cause permanent disability.[5] In addition to the health risks, these patients must expend valuable time and money that could have been avoided by remaining on their current medications.

To protect patients, CMS proposes to require insurers to provide notice to plan enrollees that they "may request and gain access to the brand drug when clinically appropriate and not otherwise covered by the health plan."[6] While this notice is helpful if a medication was excluded from the formulary, it is not necessarily helpful if a medication was moved to a higher tier, making it unaffordable for the enrollee. As such, CMS should allow individuals to request an appeal or exception if their medication has been moved to a higher tier as well. Moreover, given that plan enrollees often do not request an appeal or exception because it is too burdensome of a process, the notice should also include step-by-step instructions for filing an appeal or exception request in plain language.

II. Essential Health Benefits

CMS proposes to allow plans to exclude brand medications from the definition of essential health benefits ("EHB") if the plan also covers an equivalent generic medication that is medically appropriate for the enrollee. If a brand medication is excluded from the definition of EHB, health plans would be permitted to impose annual and lifetime caps on coverage of the brand medication or simply exclude it from coverage. Moreover, this change could result in patients being unable to access certain brand medications altogether. Additionally, it is unclear how the plan enrollee would meet the "medically appropriate" standard in order for the medication to not be excluded from the definition of EHB and whether the plan enrollee would need to prove this standard every year. Given the far-reaching implications of this proposed change, CMS should clarify these points.

Furthermore, CMS states that if an enrollee fills a prescription for a brand medication when he or she has access to a generic equivalent, then only the amount that the plan enrollee would have paid for the generic equivalent is required to count towards the annual limitation on cost-sharing. In this instance, the proposed regulation does not account for whether the brand medication is medically appropriate or not. It is inherently unfair to take a patient's money and not count it toward cost-sharing requirements, especially if the treatment is medically appropriate.

CMS also requested feedback on whether the authority to exclude brand medications should be compulsory or permissive for health plans. We recommend that CMS not exclude brand medications at all given that it could result in nonmedical switching. Furthermore, CMS requests feedback on whether such an exclusion should be considered an adverse coverage determination. We recommend that, if this proposal is implemented, it should be considered an adverse coverage determination to ensure that patients are able to utilize the appeal and exception processes to maintain access to a medically appropriate brand medication.

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[4] https://www.ajpb.com/news/multiple-sclerosis-drug-switching-may-trigger-disease-progression
[5] https://www.nationalmssociety.org/About-the-Society/Press-Room/MS-the-Disease
[6] https://www.regulations.gov/document?D=CMS-2019-0006-0016

III. Patient Assistance

CMS proposes to exclude direct patient assistance from the calculation of annual cost-sharing limits when the plan covers both a brand and generic option, and requests feedback on whether states should retain the authority to decide how direct patient assistance is handled. This proposal appears to embrace elements of harmful copay accumulator policies that have grown popular over the past two years. Excluding patient assistance from annual cost-sharing limits could result in patients losing access to medically necessary treatments.

When a pharmaceutical manufacturer provides patient assistance to an individual enrolled in a plan that offers EHBs, it is making a cost-sharing payment on behalf of the plan enrollee to the health plan. The definition of "cost-sharing" includes expenditures made "by or on behalf of" an enrollee, which suggests that manufacturers' payments should count toward the enrollee's maximum out-of-pocket costs.[7] However, if a plan excludes the value of the patient assistance from the calculation of the individual's maximum out-of-pocket costs, the plan receives the full value of the patient assistance payment without attributing any of that cost to the enrollee's maximum out-of-pocket ("MOOP") cost. By doing this, health plans can be in receipt of funds that exceed the MOOP limit, in violation of the ACA. Therefore, we urge CMS not to implement this policy, which could potentially violate existing law.

Moreover, copay accumulator programs can hurt patients. Patients with complex health conditions often resort to using patient assistance to access the specialty medications they need to maintain their health. These medications can be extremely costly, and patient assistance is not a bottomless well. A recent survey by Truven Health Analytics revealed that cost is the biggest barrier to medication adherence. Without patient assistance, many patients could become nonadherent to their medication because they may not be able to afford the out-of-pocket costs.[8] This could lead to patients skipping refills, rationing their medications, or abandoning treatment altogether.[9] The effects of medication adherence are well-known; nonadherent patients can face disease progression and increased health care utilization.[10] Uncontrolled disease progression could add stress and anxiety to the lives of people who are already vulnerable,[11] and we urge CMS to develop a better solution that protects patients instead of threatening their ability to fill their prescriptions. We recommend, if this policy is implemented, that it be considered an adverse coverage determination.

We understand that there are complexities inherent in the relationship between insurers and manufacturers, but we urge CMS to craft a policy solution that handles this issue while ensuring that patients can access the medications that are appropriate for them. We find CMS's current proposals inadequate because they sacrifice patient access in order to even the playing field between insurers and manufacturers.

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[7] https://www.law.cornell.edu/cfr/text/45/155.20
[8] https://www.webmd.com/healthy-aging/patient-assistance-programs-for-prescription-drugs#1
[9] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5538308/
[10] https://www.ncbi.nlm.nih.gov/pubmed/23229971
[11] https://pdfs.semanticscholar.org/2ce5/03b0423e5a4d46b8c7763de0d65a4a504b0e.pdf

IV. Miscellaneous

1. Silver Loading

CMS has indicated that it is interested in taking regulatory action to end the practice of "Silver Loading." Silver Loading is a tactic that marketplace health plans used to keep their premiums affordable after Cost-Sharing Reduction ("CSR") payments were halted by the current administration in 2017.[12] In particular, based on guidance from the administration, on October 12, 2017, the acting Secretary of the U.S. Department of Health and Human Services directed CMS that all CSR payments were prohibited. As a result, insurers needed a work-around to recoup lost costs. Yet, Silver Loading hurts consumers who rely on marketplace health plans for quality care, especially those who do not receive health care through their employers and do not quality for Medicare, Medicaid, or other federally funded health plans. The practice makes these plans unaffordable for the average consumer.

As such, to fix the tactic of Silver Loading, CMS should reverse its decision to prohibit CSR payments, and instead ban Silver Loading.[13] Last week, the U.S. Court of Federal Claims ruled in three separate cases, *Common Ground Healthcare Cooperative v. United States*, *Community Health Choice, Inc. v. United States*, and *Maine Community Health Options v. United States*, that the government is responsible for reimbursing health plans unpaid CSRs in 2017 and 2018.[14] The judge ruled that the government had violated the ACA's statute on CSRs and breached an implied contract. Therefore, unless Congress amends the ACA, CMS will continue to breach its obligations if it does not make CSR payments.

2. Therapeutic Substitution and Generic Substitution

CMS should not implement therapeutic or generic substitution. As CMS acknowledges, many stakeholders are opposed to therapeutic substitution, and there are concerns regarding efficacy, adverse effects, drug interactions, and different indications for drugs within a class.[15] Automatic therapeutic and generic substitution overrides a treatment decision made between the patient and provider, which could put patients' health at risk. Pharmacists are not privy to the conversations between a patient and his or her provider, and they do not have access to the patient's medical history, which could provide helpful context for why a specific medication was chosen. This proposal would weaken the doctor-patient relationship by allowing pharmacists to override the clinical judgment of prescribers. If CMS were to implement automatic substitution, it should take steps to minimize harm to patients, including by 1) requiring sufficient notice to patients and prescribers about the general policy change; 2) requiring pharmacists to honor "dispense as written" requests; 3) informing the patient at the pharmacy counter when a substitution is about to occur; and 4) providing notice to the prescriber when the substitution has taken place.

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[12] https://www.healthleadersmedia.com/finance/nearly-100-insurers-have-won-challenges-over-halted-csr-payments
[13] https://www.healthaffairs.org/do/10.1377/hblog20180613.293356/full/
[14] https://affordablecareactlitigation.files.wordpress.com/2019/02/common-ground-summary-judgment-order.pdf; https://insidehealthpolicy.com/sites/insidehealthpolicy.com/files/documents/2019/feb/he2019_0158.pdf
[15] https://www.govinfo.gov/content/pkg/FR-2019-01-24/pdf/2019-00077.pdf

3. Reference-based Pricing

CMS has requested feedback on whether it should consider reference-based pricing. As CMS notes, "reference-based drug pricing occurs when an issuer in a commercial market covers a group of similar drugs, such as within the same therapeutic class, up to a set price, with the enrollee paying the difference in cost if the enrollee desires a drug that exceeds the set (reference) price."[16]

Reference-based pricing is intended to direct patients to the lower cost treatments.[17] Oftentimes, the group of similar drugs within a therapeutic class used for setting the reference price are older, less costly treatments.[18] Yet, for many patients, a newer medication may be medically necessary. For these individuals, reference-based pricing results in balance billing. If a patient fills a prescription for a medication that exceeds the allowed amount that the payer sets on expenditures for that class of medication, the patient will be responsible for the difference.[19] As such, patients could be blindsided by the amount of money they are responsible for as a result of the reference-based pricing model. They may not be able to afford their treatment any longer and may need to switch to something that may not work for them. This is an undesirable outcome, and it creates more uncertainty for patients. As such, CMS should not adopt reference-based drug pricing.

Additionally, the success of reference-based pricing relies on patients and providers having access to up-to-date information about the prices charged by different distributors for the reference medications. Without this information, patients and providers will not be able to make the informed decisions that are required for the reference-based pricing model to save money.[20] If the class of medications used is heterogenous, patients and providers will also need to have access to quality information about the medications to make an informed decision when selecting among all of the medication options.[21]

We are not confident that the U.S. health care system has sufficient transparency measures in place to enable reference-based pricing to be successful. We request that CMS postpone its consideration of implementing reference-based pricing until greater transparency is achieved throughout the entire pharmaceutical supply chain. If CMS were to implement reference-pricing, it should allow patients to request an exception from the balance-billing requirement if a medication is medically necessary but exceeds the reference price.

4. Medication-Assisted Treatment

CMS recommends that all health plans offer comprehensive coverage of medication-assisted treatment (MAT). MAT is the use of medications, in combination with counseling and behavioral therapy, to treat substance use disorders.[22] While there have been significant efforts to

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[16] https://www.govinfo.gov/content/pkg/FR-2019-01-24/pdf/2019-00077.pdf
[17] https://www.healthaffairs.org/doi/full/10.1377/hlthaff.23.1.135
[18] https://www.healthaffairs.org/doi/full/10.1377/hlthaff.23.1.135
[19] https://www.healthgram.com/insight/pros-and-cons-of-reference-based-pricing-health-plans/
[20] https://www.commonwealthfund.org/publications/issue-briefs/2018/sep/pharmaceutical-reference-pricing-future
[21] https://www.commonwealthfund.org/publications/issue-briefs/2018/sep/pharmaceutical-reference-pricing-future
[22] https://www.samhsa.gov/medication-assisted-treatment

reduce opioid misuse, there have not been similar efforts to ensure that patients have adequate access to addiction treatment. Moreover, while MAT has been "proven to be clinically effective in treatment opioid use disorder and to significantly reduce the need for inpatient detoxification services for individuals with opioid use disorder,"[23] many health plans do not cover all of the medications approved by the U.S. Food and Drug Administration (FDA) for use in MAT. We are encouraged by and support CMS's proposal to require insurers to cover all four of these treatments.

5. Call Centers

Current regulations require health exchanges to operate a full-time call center to assist consumers with health plan enrollment. CMS proposes to eliminate the requirement that exchanges operate a call center and instead permit them to operate a toll-free hotline. CMS anticipates that providing consumers with automated responses to frequently asked questions through the toll-free hotline would provide consumers with enough information to complete their health plan enrollment. We request more information from CMS about how this will address the needs of consumers if they need to speak directly with a live person about their health plan enrollment. We request that CMS provide up-to-date data about the qualitative differences between full-time call center interactions and interactions with toll-free hotlines to allow the public to determine whether this will adequately address the needs of health plan enrollees.

V. Conclusion

We support CMS in its efforts to reduce the cost of health care; however, we caution the agency against implementing changes that limit patient access to necessary treatment. Thank you for your consideration.

Sincerely,

John Wylam
Staff Attorney

[23] https://www.govinfo.gov/content/pkg/FR-2019-01-24/pdf/2019-00077.pdf