

February 19, 2019

Alex M. Azar II  
Secretary  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-9926-P  
P.O. Box 8016  
Baltimore, MD 21244-8016

Dear Secretary Azar:

On behalf of the American Academy of Family Physicians (AAFP), which represents 131,400 family physicians and medical students across the country, I write in response to the [proposed rule](#) titled, "HHS Notice of Benefit and Payment Parameters for 2020" as published by the Centers for Medicare & Medicaid Services (CMS) in the January 24, 2019, *Federal Register*.

This proposed rule sets forth payment parameters, cost-sharing parameters; and user fees for Federally-facilitated Exchanges (FFEs) and State-based Exchanges on the Federal Platform (SBE-FPs). It also proposes policies that are intended to reduce the costs of prescription drugs, changes to Exchange standards related to eligibility and enrollment, exemptions, and other related topics. The AAFP continues to support efforts to improve patient access to affordable health insurance coverage and we offer the following comments to sections of the proposed rule that most directly impact primary care physicians and their patients.

**B. Part 147 – Health Insurance Reform Requirements for the Group and Individual Health Insurance Market**

**Summary**

CMS proposes allowing issuers on or after January 1, 2020, to make mid-year formulary changes when a generic equivalent of a prescription drug becomes available on the market. CMS further proposes that the issuer be permitted to modify its plans' formularies to add the generic equivalent drug. At that time, the issuer also would be permitted to remove the equivalent brand drug(s) from the formulary or move the equivalent brand drug(s) to a different cost-sharing tier on the formulary. Issuers also would be required to provide enrollees the option to request coverage for a brand drug that was removed from the formulary through the applicable coverage appeal process or drug exception process.

**AAFP Response**

The AAFP supports steps to reduce the costs of prescription drugs. Managing patients' prescription drug prices is an important concern for family physicians. Family physicians have a meaningful interest in the drug pricing debate, in part because of the complexity of care

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provided and the fact that the number and complexity of conditions, complaints, and diseases seen in family medicine is far greater than those seen by any other physician specialty. Ensuring access to affordable medications is an integral part of a family physician's role as an advocate for their patients.

**However, the AAFP urges caution on the use of mandatory generic substitution and removing equivalent brand drug(s) from the formulary. The AAFP believes patients should not be changed to a new product based solely on economic considerations, especially if a patient's current prescription regimen is stable.**

The AAFP agrees with the CMS proposal to allow plans to make mid-year changes that would add generic equivalent drugs to their formularies. The AAFP believes formularies should be designed to offer patients multiple levels of drug choice (from more to less restrictive) with accompanying patient cost sharing levels to account for variables including patient preferences (e.g., "direct marketing-induced" demand). However, patients should not be forced mid-year to change from a brand-named drug to a generic unless and until a physician, in consultation with the patient, decides to change to another drug. Further, the AAFP believes brand name drugs should not be moved a higher cost-sharing tier until the end of the plan year. It is important to note that patients may have selected a plan based on the affordability of a particular brand drug.

Regarding the proposal to notify the enrollee 60 days prior to initiating the change, the AAFP believes formulary changes must also be made known to physicians and pharmacies prior to implementation. The AAFP further believes notification should be 120 days prior to the change to give the physician, in consultation with the patient, ample time to make a determination about the change. Last, while the AAFP agrees with adding generics mid-year, it should be noted that the AAFP believes formularies must be stable since frequent changes create confusion and frustration for patients and physicians leading to non-compliance, adverse reactions, increased costs, and erosion of patients' confidence.

#### c. Prescription Drug Benefits (§ 156.122)

##### *Summary*

CMS asks whether it should pursue both therapeutic substitution and generic substitution policies in its quest for more efficient drug coverage. CMS asks for comments on existing standards of practice for therapeutic substitution and whether those standards are nationally recognized and readily available for use by providers.

CMS also seeks comment on the opportunities and risks of implementing or incentivizing reference-based pricing for prescription drugs.

##### *AAFP Response*

**The AAFP strongly opposes efforts to permit therapeutic substitution**, that is the substitution of a therapeutic alternate, a drug product containing a different pharmaceutical moiety, but which is of the same therapeutic or pharmacologic class. The AAFP opposes the repeal or dilution of any state or national anti-substitution laws or regulations governing the filling of the prescription from the physician by a pharmacist particularly when a prescription includes a "dispense as written" clarification. Currently, some public and private payers require pharmacists to substitute patients' prescription medications through policies such as fail first, step therapy, or drug formularies that encourage cost containment without consulting physicians or assessing patients' medical histories. These policies undermine the doctor-patient relationship by requiring less expensive medications that are therapeutically equivalent.

Regarding reference-based pricing, the AAFP appreciates CMS' efforts to lower overall health plans costs and premium increases. However, as CMS states, reference-based pricing could increase consumer out-of-pocket costs. It is well known that increasing patient cost sharing is associated with declines in medication adherence, which in turn is associated with poorer health outcomes.

**d. Prohibition on Discrimination (§ 156.125)**

*Summary*

The regulation describes how Medication-Assisted Treatment (MAT) is any treatment for opioid use disorder that includes a medication approved by the Food and Drug Administration for opioid addiction detoxification or maintenance treatment, but that there is not comprehensive, nationwide coverage of the drugs used in MAT, at least among QHP issuers.

The regulation therefore encourages every health insurance plan to provide comprehensive coverage of MAT, even if the applicable EHB-benchmark plan does not require the inclusion of all four MAT drugs on a formulary. HHS encourages issuers to take every opportunity to address opioid use disorder, including increasing access to MAT and normalizing its use.

*AAFP Response*

In the AAFP's [Chronic Pain Management and Opioid Misuse position paper](#), we call on family physicians to use protocols for MAT to address opioid dependence within the clinic population. MAT for opioid and heroin dependence has existed for more than five decades and involves some form of opioid substitution treatment. Originally, only methadone (an opioid agonist) was available, but now clinicians have buprenorphine (a partial agonist used alone or in combination with naloxone) and naltrexone (an opioid antagonist with both oral and extended-release injectable formulations) as pharmacologic options for MAT. In addition, adjunctive medications such as clonidine, nonsteroidal anti-inflammatory medications (NSAIDs), and others are used in the treatment of specific opioid withdrawal symptoms.

With the increase in opioid misuse, various federal and state authorities and professional organizations have produced guidelines to help providers best treat opioid use disorders. The AAFP encourages HHS to consult these resources and work toward a nationwide, comprehensive coverage of drugs used in MAT.

**While we applaud HHS for encouraging health insurance plans to provide comprehensive coverage of MAT, opioid misuse and addiction is a serious national crisis. The AAFP calls on HHS to require comprehensive coverage of MAT and counseling as recommended by the FDA in all public and private health insurance plans.**

Furthermore, the AAFP advocates against limits on MAT duration. Both FDA and SAMHSA state that treatment with MAT may be life-long, and we urge HHS to factor that into MAT coverage policies.

**i. Cost-sharing Requirements for Generic Drugs**

*Summary*

For plan years beginning after 2020, CMS proposes to allow plans that cover both a brand prescription drug and its generic equivalent to consider the brand drug to not be required as under essential health benefit (EHB) mandate, with some exceptions. CMS also proposes that the issuer would be permitted to ignore the difference in cost sharing between that which is paid for the brand drug and that which would be paid for the generic equivalent toward the annual limitation on cost sharing. If finalized, this interpretation would permit all group health plans and

group health insurance issuers to impose lifetime and annual dollar limits on these brand drugs because they would no longer be considered EHB subject to the prohibition on such limits.

HHS is also considering an alternate proposal, under which an issuer would be permitted to ignore the entire amount paid by a patient for a brand drug for which there is a medically appropriate generic alternative from the annual limitation on cost sharing.

#### *AAFP Comments*

It is the AAFP's position that all public and private insurance policies adhere to four fundamental patient protections – guaranteed issue, essential health benefits (EHB), limits on age rating, and no limits on annual/lifetime spending. **The AAFP does not support removing brand drugs from EHB, even if they are substituted by generic equivalents. Further, the AAFP does not support imposing lifetime and annual dollar limits on brand name drugs. Nor does the AAFP support ignoring the entire amount paid for brand drugs or the difference in cost sharing between brand and generic drugs in the calculation of a patient's annual limitation on cost sharing.**

In our extensive [policy on generic drugs](#), the AAFP recognizes that FDA-approved generic medications may be reasonable alternatives to brand name medications. While generic substitution may often be clinically appropriate and an effective measure to help allocate scarce resources, **the AAFP opposes mandatory generic substitution. The AAFP strongly supports the elimination of prior authorizations (PA) for generic drugs. The AAFP believes that this type of administrative burden undermines the doctor-patient relationship and lowers quality of care.**

The AAFP supports affordable generic medications and believes such medications should be readily available for family physicians to prescribe. However, patients on stable drug regimens should not be forced to change to a new product based solely on economic considerations.

#### ii. Cost-sharing Requirements and Drug Manufacturers' Coupons

##### *Summary*

CMS proposes, for plan years beginning on or after January 1, 2020, that amounts paid toward cost sharing using any form of direct support offered by drug manufacturers to insured patients to reduce or eliminate immediate out-of-pocket costs for specific prescription brand drugs that have a generic equivalent are not required to be counted toward the annual limitation on cost sharing. CMS believes not counting such amounts toward the annual limitation on cost sharing would promote: (1) prudent prescribing and purchasing choices by physicians and patients based on the true costs of drugs and (2) price competition in the pharmaceutical market.

##### *AAFP Comment*

Per our [policy on patient-centered formularies](#), the AAFP is concerned that certain ownership and/or financial arrangements among pharmaceutical manufacturers, pharmacy benefit management (PBM) organizations, mail order companies, health plans, retail pharmacies, pharmacists and other provider groups could create conflicts of interest or financial incentives which may not be in patients' best interests, e.g. manufacturer discounts and/or rebates for the utilization of certain drugs. They may also result in compromised quality of care, excessively high premiums, and "out of pocket" costs.

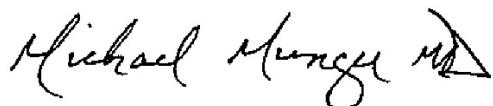
The AAFP is concerned that direct support offered by drug manufacturers (ex. coupons) only temporarily reduces a patient's upfront costs for brand named drugs. This steers the patient away from less expensive generics when already available. Coupons entice patients to obtain

the brand name drug because the patient's out of pocket costs are reduced, yet health insurers are still forced to pay for the brand name drug. They in turn likely push the cost of paying for expensive brand name drugs to patients through increased premiums. Ultimately, the patient pays more, just in a different way.

The AAFP recently supported CMS proposal to require the inclusion of drug pricing information and lower cost therapeutic alternatives in the Explanation of Benefits (EOB) that Part D and Part C plans send members. In the spirit of transparency, the AAFP believes the true cost of a prescription drug should count toward the annual limitation on cost sharing

We appreciate the opportunity to comment. Please contact Robert Bennett, Federal Regulatory Manager, at 202-655-4908 [rbennett@aafp.org](mailto:rbennett@aafp.org) with any questions or concerns.

Sincerely,



Michael L. Munger, MD, FAAFP  
Board Chair

### **About Family Medicine**

Family physicians conduct approximately one in five of the total medical office visits in the United States per year—more than any other specialty. Family physicians provide comprehensive, evidence-based, and cost-effective care dedicated to improving the health of patients, families, and communities. Family medicine's cornerstone is an ongoing and personal patient-physician relationship where the family physician serves as the hub of each patient's integrated care team. More Americans depend on family physicians than on any other medical specialty.