

DEPARTMENT OF INSURANCE**Executive Office**

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February 19, 2019

Submitted via www.regulations.gov

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-9926-P
P.O Box 8016
Baltimore, Maryland 21244-8016

SUBJECT: Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2020
File Code: CMS-9926-P

Dear Administrator Verma:

As California's Insurance Commissioner it is my privilege and responsibility to regulate the nation's largest insurance market and lead the largest consumer protection agency in the state, the California Department of Insurance (CDI). Passage of the Affordable Care Act (ACA) was one of the most significant Congressional, legislative, and regulatory acts of the last fifty years. California has been a leader in the successful implementation of the ACA.

CDI implements and enforces the consumer protections provided by the ACA and codified into state law, such as essential health benefit requirements, anti-discrimination protections, and laws pertaining to access to health care. The comprehensive health insurance coverage intended by the ACA provides access to preventive care and other essential health benefits and enables Californians to maintain wellness and be confident that they will receive necessary treatment when needed without financial catastrophe. Millions of Californians have had their health and economic security improved as a result of the ACA. Adequate, affordable, and accessible health insurance is essential, as it provides hope for health and well-being, as well as peace of mind for Californians and their families.

As I will detail below, certain provisions of the proposed *Notice of Benefit and Payment Parameters for 2020* threaten the financial security and health of Californians and others throughout our nation. In previous years, annual changes to federal regulations made in the Notice of Benefit and Payment Parameters have not been used as an opportunity to wreak havoc on the Affordable Care Act. These proposed regulations include a number of provisions that would be destructive to health insurance markets and could cause Californians and those throughout the country to lose their coverage or find it unaffordable. I urge you to withdraw the portions of these proposed regulations that make such significant and harmful changes.

1) 84 FR 229, Automatic Re-enrollment

CDI opposes CMS' proposal to stop automatically re-enrolling insureds in their health insurance coverage. Adopting this proposal will result in a massive market disruption and increase health insurance rates due to a smaller risk pool. Insureds are accustomed to auto re-enrollment. Particularly with the shortened open enrollment period, consumers may fail to realize that they are not automatically re-enrolled in coverage until it is too late, and will lose their coverage, rendering them unable to enroll in any coverage for an entire year.

This proposal directly conflicts with the guaranteed renewability provisions found in federal statute and would result in cancellation of health insurance outside the events cited in 42 USC § 300gg-2. This proposal should not be adopted; individuals should be reenrolled in the same policy so long as that policy is not being discontinued or withdrawn from the market unless the consumer selects other coverage.

CDI is concerned about any action that would depress enrollment and create ripples of uncertainty among consumers, as this uncertainty and consumer confusion could depress enrollment even in states, such as California, that do not use the federal platform.

2) 84 FR 230, Promoting High Deductible Health Plans and Health Savings Accounts

Health savings accounts (HSAs) and High-Deductible Health Plans (HDHPs) are of no use to the many Americans who live from paycheck-to-paycheck and cannot afford to store money away in an HSA. Further, the use of HDHPs and HSAs is detrimental to the chronically ill. First, chronically ill individuals cannot store money away in HSAs while simultaneously maintaining their treatment regimen. In addition, HDHPs do not provide coverage until a deductible has been met. An HDHP may actually incentivize chronically ill individuals to defer care until their condition deteriorates sufficiently to necessitate expenditure of the full deductible, rather than incur the economic burden of the deductible to maintain their regimen. Such deferred care increases morbidity, and therefore increases costs over time. These costs are not just borne by the health insurance industry, but also the work force through missed work days. Rather than promoting HSAs and HDHPs, CMS should instead be spending its resources on increasing affordability, decreasing consumer confusion, and making health insurance coverage accessible to all.

3) 84 FR 234-35 & 313-14, Guaranteed Renewability of Coverage (§ 147.106)

CDI supports the proposal to permit issuers to implement mid-year coverage transitions to new generic drugs, but only when the generic offers out-of-pocket savings over the brand name equivalent drug due to lower tier placement in the formulary. CDI also supports applying this rule to large group health insurance products because those products are subject to the same prohibition on mid-year changes to coverage, and implicate the same consumer reliance concerns in having access to stable benefits, as health insurance offered in other market segments. However, CDI agrees with the NAIC that CMS should limit mid-year formulary changes for

brand name drugs with newly approved generic equivalents to tier placement changes and not permit issuers to remove brand name drugs from the formulary altogether in the middle of a plan year. Issuers should be prohibited from removing any drug from a formulary during a plan year.

CDI also agrees with the NAIC that the noticing requirements in the proposal should be strengthened by requiring a two-phase noticing approach. The first notice would advise covered persons of the availability of the generic equivalent drug and the out-of-pocket cost savings that will be available by switching to the generic drug to provide them with sufficient time to plan for changing their prescription. After 90 days has elapsed since the first notice was provided, the second notice would then advise covered persons that the out-of-pocket cost for the brand name drug will increase in 60 days. Only after 60 days have elapsed from the second notice would the issuer then be permitted to change the tier placement of the brand name drug to increase out-of-pocket costs. This two-phase noticing approach balances consumers' reliance interests in having access to stable benefits with issuers' interests in transitioning covered persons to less expensive generic equivalents for brand name drugs.

It is unclear why CMS proposes to require mid-year generic drug transitions to conform to the scope of a uniform modification of coverage under 45 CFR § 147.106(e)(3), which determines the extent of plan changes at renewal that trigger a discontinuation and applies only to individual and small group products. The preamble did not explain the reasoning for applying (e)(3) or how it would be applied in practice, but we assume the applicable standard would be (e)(3)(v) on changes to covered benefits.

Requiring mid-year formulary changes to comply with the standard in (e)(3)(v) is inconsistent with the proposal because cumulative changes in benefits that result in a greater than +/-2% effect on the plan-adjusted index rate are outside the scope of a uniform modification of coverage. Because the objective of the proposal is to permit realization of savings from mid-year generic drug approvals, applying that standard is at cross-purposes, as it would limit the amount of savings that could be realized.

Further, as noted in the preamble, the subdivision (e)(3) standard for a uniform modification of coverage does not apply to large group products. Because large group products are not subject to the requirement to establish an index rate under 45 CFR § 156.80, it is unclear why CMS proposes to require large group products to comply with 45 CFR § 147.106(e)(3) for mid-year generic drug transitions, and how this requirement would be applied in practice. However, CDI agrees with requiring mid-year generic drug transitions in individual and small group products to comply with (e)(1) and (e)(2) because the change should be effective uniformly and consistent with state law.

Applying subdivision (e)(3) to mid-year generic drug transitions will not protect consumers from excessive or negative tiering changes that increase their out-of-pocket costs. It is unlikely that the limit on benefit changes would ever be triggered, but if it were, it would limit realization of savings from generic drug substitutions without protecting consumers from adverse tier placement changes. To ensure that consumers benefit from mid-year coverage transitions to new

generic drugs, CMS should instead add regulatory text explicitly requiring that the generic drug not be placed on the same or a higher tier than the tier on which the brand name drug is placed. If the generic drug is not placed on a lower tier than its brand name equivalent, consumers will not realize any cost savings resulting from the addition of the generic drug to the formulary. As recognized by CMS in other prescription drug proposals it has recently made, it is only fair that issuers should share savings generated from lower prescription drug prices with their members. If the generic drug does not offer any cost savings over the equivalent brand name drug, there is no reason to require consumers to transition from the brand name drug in the middle of the plan year.

If CMS decides not to require the newly added generic drug to be placed on a lower cost sharing tier than its brand name drug equivalent, at a minimum it should adopt explicit language prohibiting the generic drug from being placed on a higher cost sharing tier. Without this restriction, issuers would be permitted to violate consumer's reliance interests in having access to stable benefits throughout the plan year by implementing mid-year generic drug substitutions that impose higher out-of-pocket costs. Such negative mid-year formulary changes are not permitted in Medicare Part D and should not be permitted in products subject to the ACA.

In conclusion, CDI supports this proposal if it is revised so that mid-year generic drug coverage transitions are not subject to the uniform modification of coverage standards in subdivision (e)(3). Instead of applying (e)(3), which does not protect consumers from negative mid-year formulary changes that increase their out-of-pocket costs, CMS should adopt regulatory text that requires the cost sharing for the generic drug to be less than for the brand equivalent drug. Additionally, CMS should require a longer two-phase noticing approach as advocated by the NAIC and described above.

4) 84 FR 251, Risk Adjustment Issuer Data Requirements (§§ 153.610 & 153.710)

CMS seeks comments on whether it should extract state and rating area information for enrollees as part of the enrollee-level EDGE data. CDI supports the inclusion of these data elements as part of the data available to qualified requestors. This data would be very useful for public health research, and transparency, and would also help state departments of insurance to be more informed in their rate review processes.

CMS also seeks comment regarding the use of state and rating area information for recalibration of the risk adjustment program, AV Calculator and methodology, and other market programs. CDI opposes incorporating rating area information into the Actuarial Value (AV) calculator, as this addition would add additional complexity without commensurate benefit, and could potentially require insurers to create different plans for different rating regions.

5) 84 FR 283, Silver Loading

In 2017, CSR payments were discontinued by the Trump Administration in violation of the ACA, which provides for these payments. In response to the termination of CSR payments,

issuers in many states used actuarial loading, also referred to as “silver loading,” which increased premiums on silver level plans within the exchanges to compensate for the unfunded CSR payments. The loss of CSR payments threatened the exchange markets with immediate destabilization, which would have resulted in loss of coverage options and increases in premiums. Had the “silver loading” not taken place, issuers might have quickly exited the individual market, leaving people without the ability to purchase health insurance coverage. Instead, through the use of “silver loading”, states were able to stabilize their markets in a way that improved the coverage options available to subsidized enrollees. “Silver loading” also improved the risk mix in exchange plans, as it made coverage more affordable.

CDI urges that, in the absence of Administrative or Congressional action resuming CSR payments, CMS either adopt the existing practice, or take no administrative action. Any changes to the existing practice will only destabilize insurance markets that have recently achieved a beneficial equilibrium despite the Administration’s actions. Interfering with the ability of states to address the destabilizing act the Trump Administration took in withholding the CSR payments with remedies such as “silver loading” will increase premiums or cause issuers to stop selling health insurance in the individual market, and would cause millions of Americans to lose their health insurance.

6) 84 FR 284, Prescription Drug Benefits (§ 156.122)

CDI does not support a policy permitting issuers to impose therapeutic substitution because drug choice decisions should be made by a physician based on applying clinical expertise and judgment to each patient’s individual circumstances. Not all drugs in the same therapeutic class work by the same biological mechanism. Even if multiple drugs in the same class do work by the same mechanism, the drugs will not always produce the same efficacy in different individuals. Further, drugs in the same class have different side effects that can make one drug preferable to another for a particular individual. This policy would empower issuers to substitute their judgment for that of a patient’s doctor in complex clinical decisions.

Generic substitution is permitted because the brand name drug and its generic equivalent have identical active ingredients, strength, and formulation, while therapeutic substitution has a much greater potential to cause adverse health consequences. Additionally, bureaucratic delays in access to prescription drugs caused by medically inappropriate therapeutic substitution occurring at the pharmacy could increase adverse health consequences for consumers.

When issuers determine that a drug is a lower cost and effective alternative for another drug, they are already permitted to omit drugs from a formulary and require step therapy. Issuers should not be permitted to interfere in individual prescribing decisions beyond exercising their prerogative to exercise reasonable medical management. Therapeutic substitution is not a reasonable medical management technique, and we believe changes in statutory law would be required to allow pharmacists and issuers to engage in this ill-advised policy.

7) 84 FR 285-88 & 308, Premium Adjustment Percentage (§ 156.130)

CDI strongly opposes CMS's proposal to change the source of premium data used to calculate the premium adjustment percentage. This proposed change will have widespread adverse effects on the market, as the premium adjustment percentage is used to index the annual limit on cost-sharing, the required premium contribution percentage and the employer shared responsibility payment amounts. In the past, CMS correctly chose not to include the individual market premiums in the index when calculating the premium adjustment percentage due to the initial instability in individual market premiums. Rather than continuing to exclude the individual market from the index, CMS now proposes to change the measure of premium growth used to calculate the premium adjustment percentage to include individual market premiums, arguing that the proposed index is a more accurate reflection of premium growth.

Using a measure of premium growth that factors in the fluctuation in individual market premiums due to implementation of the ACA's market reforms is not more accurate because it captures more than premium trend caused by increases to health care costs. By including individual market premiums, initial individual market premium increases that were unrelated to increases in health care costs will be added to the index, injecting instability into the group markets and increasing instability in the individual market.

This change will result in lower premium tax credits and loss of coverage for consumers who rely on the premium tax credit to afford health insurance, and higher out-of-pocket maximums, which adversely impacts access to care for less healthy individuals with high health care expenses who need the protection of the out-of-pocket maximum. CMS, by its own estimates at 84 FR 308, anticipates that the change in the index will have widespread negative consequences: an estimated 100,000 fewer people with coverage, premium increases, increases in employer shared responsibility payments, decreases in premium tax credits, and increases in health insurance taxes. CDI strongly urges CMS to withdraw this extremely damaging proposal, in order to avoid the negative consequences that CMS itself predicts will occur if the proposed index is adopted.

8) 84 FR 289-91 & 320, Application to Cost-Sharing Requirements and Annual and Lifetime Dollar Limitations (§ 156.130)

CDI opposes CMS's proposal to permit issuers to exclude a brand drug that has an available generic equivalent from the definition of an EHB, even when the brand drug is covered. Permitting issuers to pick and choose which of the drugs they cover as EHBs will severely undermine the ACA's prohibition on annual and lifetime dollar limits on EHBs and cause excessive disruption and confusion for consumers and regulators.

The EHB minimum drug count requirement would never require a brand drug with an available generic equivalent to be covered because the requirement applies only to chemically distinct drugs. Issuers are already able to omit brand drugs with generic equivalents from a formulary or place them on a higher cost sharing tier than their generic counterparts. These commonly

employed medical management techniques, in addition to state laws that permit generic substitution, already encourage the use of lower cost generic equivalents. Consequently, this proposal is entirely unnecessary and appears to be another attempt by the Administration to weaken the consumer protections of the ACA by allowing dollar limits to apply to prescription drugs that an issuer chooses to cover voluntarily.

Any brand drug that an issuer elects to keep on its formulary following the introduction of a generic equivalent to the market should be covered as an EHB. Most consumers would be unaware that the difference in cost sharing between a brand drug and its generic equivalent does not count toward the out-of-pocket maximum, which is unfair when an issuer has elected to cover both drugs. Issuers should be incentivized to properly manage their formularies and implement a generic drug substitution process at network pharmacies rather than shifting costs of brand drug utilization on unsuspecting consumers.

This proposal should be withdrawn because there are already mechanisms through which issuers can encourage the use of available generic equivalents without causing harm to consumers by excluding cost sharing for a covered drug from accruing to the out-of-pocket maximum. Moreover, permitting issuers to impose annual and lifetime limits on covered drugs is inconsistent with the ACA, and could have serious consequences for consumers with chronic conditions.

If this proposal is adopted, CDI strenuously opposes preemption of state law. The regulation text should expressly provide that it applies only to the extent consistent with state law.

If this proposal is adopted, CMS should require issuers who choose to follow this policy when permitted by state law to disclose it to consumers in insurance policies and in a separate notice, including providing a list of covered brand name drugs with generic equivalents that are subject to the policy. The regulation should also explicitly state that exclusion of any amount of cost sharing from accruing to the out-of-pocket maximum is an adverse coverage determination subject to the appeals process in 45 CFR § 147.136, and that notice of appeal rights must be provided to an affected consumer whenever cost sharing is excluded from the out-of-pocket maximum. Robust notice requirements would mitigate the surprise negative effects of this policy by giving consumers notice and an opportunity to consider the consequences of continuing to take a brand name drug when a generic equivalent is available.

Finally, we note that the proposed text includes a critical error at 45 CFR § 156.130(h)(1)(i): the word “alternative” is used instead of “equivalent.” This error must be corrected to avoid any confusion between a generic *equivalent* to a brand name drug and a generic *alternative*.

The second proposal to permit issuers to exclude manufacturer coupons for brand name drugs that have a generic equivalent from accruing to the out-of-pocket maximum implicitly assumes that the generic drug is less expensive and thus that the coupon is distorting the market. Generic

drugs, especially the first approved generic, are not always appreciably less expensive than their brand name counterparts.¹

California recently passed a law to prohibit drug manufacturers from offering coupons for a brand name drug when a lower cost generic equivalent is covered on a lower cost-sharing tier than the brand name drug. The law also includes important exceptions for drugs that are subject to a REMS program or when an issuer has authorized coverage for the brand name drug after an individual has satisfied a prior authorization or step therapy requirement (Cal. Health & Saf. C. §§ 132000 & 132004). If adopted, CMS should consider whether such exceptions to this rule are warranted, including that a brand name drug coupon should be permitted to count toward the out-of-pocket maximum when the generic alternative is not less expensive for the consumer based on the generic drug's tier placement in the issuer's formulary. We also oppose preemption of state law on this topic.

Additionally, there are omissions in the proposed text that need to be corrected. The rule should only apply when a generic equivalent is available on the market and covered by the issuer, as not all FDA-approved generics are brought to market. The rule should also include an exception for when an issuer has authorized coverage of the brand name drug due to medical necessity.

Finally, if this proposal is adopted, issuers should be permitted to exclude manufacturer coupons only at the point-of-sale, as allowing funds that were already accepted at the pharmacy to be excluded from the out-of-pocket maximum could incent abusive issuer practices.

9) 84 FR 320, Rules Relating To Coverage Of Abortion Services And Segregation Of Premiums For Such Services (§ 156.280)

I urge you to withdraw the amendments to the rules relating to coverage of abortion services and segregation of premiums for such services in the proposed rule. The clear purpose of the proposed addition of paragraph (c)(3) to 45 CFR § 156.280 is to interfere with access to abortion and decrease access to plans with abortion coverage, and it also has the potential to create substantial consumer confusion.

The proposed amendment in the proposed rule is inappropriate and extraordinarily burdensome to consumers and health insurers. As the preamble to the proposed rule notes, each state currently regulates the required benefits in QHP offerings. Further, section 1303(b)(1)(A)(ii) of the Patient Protection and Affordable Care Act, codified as 42 USC § 18023, states that if a state has not prohibited abortion coverage on the Exchange, “the issuer of a qualified health plan shall determine whether or not the plan provides coverage” of abortion services as part of the EHB covered by the QHP. The preamble conflicts with this clear language in the law granting sole discretion to determine coverage of abortion services to QHP issuers in the absence of state law restricting or requiring such coverage. Instead, CMS simply states that issuers' rights would not

¹ FDA Center for Drug Evaluation and Research, *Generic Competition and Drug Prices*, available at <https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm129385.htm>.

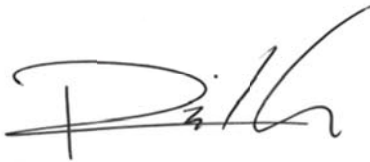
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be undermined by the proposed requirement that issuers providing coverage of abortion services also offer a mirror QHP excluding abortion coverage. This statement is both untrue and completely disregards the direct and likely impact of the proposed rule. Faced with a requirement to increase QHP plan offerings and duplicate administrative efforts, issuers will likely stop offering plans with abortion coverage altogether in states where there is no requirement to cover abortion. This will immediately impact thousands of families who will face the burden of paying out-of-pocket for medically necessary reproductive health care services. And while the cost will be borne by families of all types, the blocking of access to critical reproductive health care services creates a disparate and discriminatory impact on women.

The plain language of 42 USC § 18023(b)(1)(A)(ii) prohibits this proposed amendment to 45 CFR § 156.280. The proposal defies the statute, is complex and extraordinarily burdensome to both consumers and issuers, and would lead to increased cost and decreased access to reproductive health care services for women. CDI strongly opposes the proposed amendment.

Thank you for your consideration of these comments.

Sincerely,

A handwritten signature in black ink, appearing to read "Ricardo Lara". The signature is stylized with a large, sweeping initial "R" and a long horizontal line extending to the right.

RICARDO LARA
Insurance Commissioner

cc: California Congressional delegation