



September 13, 2021

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Center for Consumer Information & Insurance Oversight
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Jeff Wu
Deputy Directory of Policy
Center for Consumer Information & Insurance Oversight
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Re: Essential Health Benefits Scheme

Dear Mr. Grant and Mr. Wu:

Aimed Alliance is a 501(c)(3) non-profit health policy organization that seeks to protect and enhance the rights of health care consumers and providers. The Center for Health Law and Policy Innovation of Harvard Law School (“CHLP”) advocates for legal, regulatory, and policy reforms to improve the health of underserved populations, with a focus on the needs of low-income people living with chronic illnesses and disabilities.

It has recently come to our attention that some companies that are partnering with insurers and misleading patients by calling themselves “patient services hub centers” are likely violating the Patient Protection and Affordable Care Act (“ACA”). Thus, we are asking that the Center for Consumer Information and Insurance Oversight:

- (1) Confirm our interpretation that if a health plan, including an employer-sponsored health plan, covers a prescription drug, drug is considered an essential health benefit (“EHB”);**
- (2) Determine that patient services hub centers are violating the ACA and its implementing regulations; and**
- (3) Take enforcement action against these companies if they are violating the ACA or provide a frequently asked questions (“FAQ”) on the issue.**

Finally, we request a virtual meeting to discuss this matter further.

I. Patient services hub centers have created a new industry that exploits a loophole in ACA

We are concerned that companies that refer to themselves as “patient services hub centers” (“Hub Centers”) are misinterpreting EHB protections in the ACA to the detriment of patients. A “hub” generally acts as an intermediary between various members of the distribution chain and the consumer.¹ There are a variety of hub models; however, “patient services hub centers” typically

¹ <https://www.pharmaceuticalcommerce.com/view/2015-hub-services-report>

refers to hubs that contract with drug manufacturers to provide services to patients so that patients can access their medications and adhere to their treatment plan.² Here, Hub Centers, such as SaveonSP, are partnering with insurance companies and pharmacy benefit managers (PBMs) to administer a program in which they claim to have found a legal loophole to EHB protections.³ The ACA's EHB requirement ensures that a certain minimum number of medications in each class and category of drugs are covered and subject to annual maximum out-of-pocket limits on cost-sharing.⁴ These protections help to ensure that consumers can access and afford medically necessary therapeutics. However, SaveonSP's program (described as "a non-essential health benefits copay assistance solution" and a "copay offset program from specialty medication")⁵ "utilizes plan-design changes to identify select drugs as non-essential health benefits, enabling maximum savings and reducing plan and member costs" for employer-sponsored health plans.⁶ Under this program, specialty medications listed on SaveonSP's drug list are available for a \$0 copay for plan enrollees who sign up.⁷ Once the plan enrollee is enrolled in SaveonSP's plan, the plan collects the maximum amount of copay assistance from the manufacturer and does not count that copay assistance toward the plan enrollee's deductible, essentially serving as a copay maximizer program.⁸

However, if the enrollee does not sign up, the enrollee is responsible for a much higher copay.⁹ SaveonSP states that the copays "may vary based on the manufacturer allowed amounts for a particular specialty prescription drug."¹⁰ In other words, copay amounts are determined based upon the maximum value that a manufacturer has set for a copay assistance program. The copays for several medications, for example, are set at \$7,500 per fill.¹¹ That copay does not count towards the plan enrollee's deductible, or the annual maximum out-of-pocket limit as established by the ACA. Instead, the plan enrollee is responsible for that copay for the entirety of the plan year, unless they enroll in SaveonSP's program.¹² Therefore, a monthly medication with a \$7,500 copay could cost a plan enrollee \$90,000 per year if they do not sign up. That is \$81,450 over the annual limit for individuals and \$72,900 over the limit for family health plans.¹³

SaveonSP has argued that it is permitted to charge plan enrollees more than the ACA maximum out-of-pocket limit because it has determined that the specialty drugs on its list are "covered" but not EHBs.¹⁴ SaveonSP has come to this conclusion based on two arguments. First, it claims that specialty medications are not one of the ten categories of EHBs.¹⁵ Second, it argues that

² <https://www.pharmaceuticalcommerce.com/view/finding-the-hub-in-specialty-pharma-services>

³ <https://www.express-scripts.com/corporate/solutions/lowering-costs#saveonsp>

⁴ <https://www.drugchannels.net/2020/02/latest-express-scripts-data-slow-drug.html>

⁵ <https://www.express-scripts.com/corporate/solutions/lowering-costs#saveonsp>

⁶ <https://www.express-scripts.com/corporate/solutions/lowering-costs>

⁷ <https://www.strsoh.org/news/health-care/2021/saveonsp-program-added-for-some-specialty-medications.html>

⁸ <https://www.iona.edu/offices/human-resources/employee-benefits/health-insurance/saveonsp-variable-copayments-certain>

⁹ <https://www.strsoh.org/news/health-care/2021/saveonsp-program-added-for-some-specialty-medications.html>

¹⁰ https://www.strsoh.org/_pdfs/health-care/saveonsp.pdf

¹¹ https://www.strsoh.org/_pdfs/health-care/saveonsp.pdf

¹² <https://www.strsoh.org/news/health-care/2021/saveonsp-program-added-for-some-specialty-medications.html>

¹³ <https://www.healthcare.gov/glossary/out-of-pocket-maximum-limit/>

¹⁴ <https://www.iona.edu/offices/human-resources/employee-benefits/health-insurance/saveonsp-variable-copayments-certain>

¹⁵ <https://www.aps.edu/human-resources/benefits/documents/2021-summary-of-benefits/express-scripts-summary-of-benefits>

an insurer is only required to cover the same *number* of drugs within a class and category as the state’s benchmark health plan. Therefore, any additional medications that a plan covers within those classes and categories are not considered an EHB and not subject to the ACA’s out-of-pocket maximums.¹⁶

II. The EHB Scheme Violates the ACA and Its Implementing Regulations

SaveonSP’s scheme violates the ACA and its implementing regulations because employer-sponsored health plans that choose to offer prescription drugs must comply with the ACA annual limits on cost-sharing, with certain exceptions that do not apply here.¹⁷

A. Specialty medications are prescriptions drugs—an EHB

SaveonSP argues that the “specialty medications” subject to its program do not fit within the existing 10 categories of EHBs.¹⁸ However, prescriptions drugs is one of the categories of EHBs.¹⁹ While the ACA does not define the term “prescription drugs,” the ACA regulation governing prescription drugs as an EHB refers to “FDA-approved drugs.”²⁰ The FDA defines a “prescription drug” as “any human drug required by Federal law or regulation to be dispensed only by a prescription. . . .”²¹ Likewise, the plain meaning of the word “prescription drug” is a “drug that can be obtained only by means of a [health care practitioner’s] prescription.”²² Moreover, the ACA regulations only mention one class or category of drugs that health plans may choose not to cover as an EHB—drugs intended for abortion.²³ Each of the specialty medications listed in SaveonSP’s drug list requires a prescription in order to be dispensed or administered.²⁴ None of them appear to be for abortion.²⁵ Therefore, all of the specialty medications subject to SaveonSP’s program fit within the EHB category of “prescription drugs.”

B. Covered prescription drugs are EHBs and must count toward annual cost-sharing limits

Under the ACA, all EHBs, including prescription drugs, are subject to the annual limits on cost-sharing, unless an exception exists.²⁶ Cost-sharing includes deductibles, coinsurance,

¹⁶ <https://www.express-scripts.com/corporate/articles/reducing-specialty-drug-costs>

¹⁷ 42 U.S.C §18022(b); 42 C.F.R. §156.122

¹⁸ <https://www.aps.edu/human-resources/benefits/documents/2021-summary-of-benefits/express-scripts-summary-of-benefits>

¹⁹ 42 U.S.C §18022(b); 42 C.F.R. §156.122

²⁰ 42 C.F.R. 156.122(a). This regulation states that in order for prescription drugs to be considered an EHB, the plan must use a pharmacy and therapeutic (P&T) committee that meets certain standards. These standards include a review of new and existing FDA-approved drugs. As such, the term “prescription drugs” likely refers to FDA-approved drugs.

²¹ 21 C.F.R. 205.3(e)

²² <https://www.merriam-webster.com/dictionary/prescription%20drug>

²³ 42 C.F.R. 156.122(b)

²⁴

<https://www.ccssoh.us/site/handlers/filedownload.ashx?moduleinstanceid=8821&dataid=32394&FileName=SaveOn%20Drug%20list%20July%201%202021.pdf>

²⁵

<https://www.ccssoh.us/site/handlers/filedownload.ashx?moduleinstanceid=8821&dataid=32394&FileName=SaveOn%20Drug%20list%20July%201%202021.pdf>

²⁶ <https://www.cms.gov/CCIIO/Resources/Files/Downloads/ehb-faq-508.pdf> at p. 4 Exceptions include ng coverage is for premiums, balance billing for non-network, or spending on non-covered services

copayments, and similar charges.²⁷ Employer-based plans are not required to offer EHBs.²⁸ However, if an employer-sponsored plan chooses to offer an EHB, the EHB coverage must comply with ACA requirements.²⁹

ACA regulations state a health plan provides essential health benefits for prescription drugs only if it “covers ***at least the greater*** of (1) one drug in every USP category and class; or (2) the same number of prescription drugs in each category and class as the benchmark plan.”³⁰ By using the “at least the greater” language, the regulation sets a ***minimum*** standard of what a plan must cover to offer prescription drugs as an EHB rather than an upper limit. This interpretation is consistent with other provisions within the same regulation. For example, the regulation provides that a health plan must offer appropriate means for an individual to request and receive appropriate clinical prescriptions that are not covered under the general plan (i.e., an exception request).³¹ The exception provision says that the plan “must treat the excepted drug(s) as an essential health benefit, including by counting any ***cost-sharing toward the plan’s annual limit on cost-sharing***. . . .”³² It would be inconsistent for excepted drugs to be considered an EHB while other drugs that are covered by the plan are not considered EHBs. Similarly, in discussing charging different cost-sharing amounts for obtaining a covered drug at a retail pharmacy, the regulation says, “***all cost sharing will count toward the plan’s annual limitation on cost sharing***,” again conveying that all covered drugs are to be treated as EHBs for the purpose of calculating the annual cost sharing limitation.³³

Moreover, HHS has confirmed this interpretation, at least as it applies to small and individual group plans. In the Notice of Benefit and Payment Parameters for 2016 (“NBPP 2016”), HHS stated that “plans are permitted to go beyond the number of drugs offered by the benchmark without exceeding EHB. Therefore, if the plan is covering drugs beyond the number of drugs covered by the benchmark, ***all of these drugs are EHB and must count towards the annual limitation on cost sharing***.”³⁴ This position was also reaffirmed by HHS in the NBPP 2020.³⁵

Employer-sponsored health plans that use the services of Hub Centers like SaveonSP provide voluntary coverage of prescription drugs. All covered drugs offered by these plans are EHBs, and therefore, such plans are required to comply with the ACA’s annual limit on cost-sharing. However, SaveonSP and other Hub Centers are incorrectly defining EHBs by misconstruing the “at least the greater” language to mean that only the minimum number of medications must be covered as an EHB, and therefore, the remainder of the medications are not considered EHB.³⁶ This interpretation is incorrect because the regulation explicitly provides a manner for non-benchmark medications to be considered an EHB. Moreover, the operation of SaveonSP’s policy goes directly against the language of the statute that states “***all cost sharing will***

²⁷ 42 U.S.C §18022(c)

²⁸ <https://www.cms.gov/ccio/resources/files/downloads/ehb-faq-508.pdf>

²⁹ <https://www.cms.gov/ccio/resources/files/downloads/ehb-faq-508.pdf>

³⁰ 42 C.F.R. 156.122

³¹ 42 C.F.R. 156.122

³² 42 C.F.R. 156.122

³³ 42 C.F.R. 156.122

³⁴ govinfo.gov/content/pkg/FR-2015-02-27/pdf/2015-03751.pdf at p. 69 (emphasis added).

³⁵ <https://www.federalregister.gov/documents/2019/04/25/2019-08017/patient-protection-and-affordable-care-act-hhs-notice-of-benefit-and-payment-parameters-for-2020>

³⁶ <https://www.drugchannels.net/2020/02/latest-express-scripts-data-slow-drug.html>

count toward the plan's annual limitation on cost sharing."³⁷ Thus, if an individual is prescribed a covered medication, the medication must be considered an EHB and subject to the cost-sharing limits.

C. Employer-sponsored plans can define an EHB so long as the definition complies with pre-established definitions and guidance, statutes, and regulations.

Hub Centers, such as SaveonSP, are using an impermissible definition of "EHB" that is inconsistent with U.S. Department of Health and Human Services ("HHS") guidance.

In 2011, HHS issued guidance defining EHBs.³⁸ This guidance provided that under the ACA, large group health plans and self-insured health plans are not required to offer EHBs.³⁹ However, as stated above, if they do choose to offer an EHB, ACA limits on cost-sharing apply to them.⁴⁰ HHS also stated that such plans could impose certain limits on benefits "that do not fall within the definition of EHB."⁴¹ However, the guidance stated that large group health plans and self-insured plans may only modify the definition of EHB in a manner "that is authorized by the Secretary of HHS."⁴² Furthermore, the guidance said that the Departments of Labor, Treasury, and HHS "intend to use their enforcement discretion and work with those plans that make a good faith effort to apply an authorized definition of EHB."⁴³

In 2014, HHS amended the definition of EHB, authorizing a narrow carve-out for EHB coverage requirements in self-insured and large group plans.⁴⁴ The carve-out permitted plans to exclude the cost of name brand prescriptions towards the out-of-pocket maximum when a medically appropriate generic version is available.⁴⁵ The guidance did not define any other carve-outs, nor did it leave room for inferences regarding additional exceptions that could be derived from this narrow exclusion. Therefore, HHS has only authorized one deviation to the standard definition of EHB (i.e., excluding brand drugs if a generic exists). However, SaveonSP's definition of EHB is based on the number of drugs offered in a state's benchmark health plan. HHS has not released any guidance permitting this interpretation.

SaveonSP and similar Hub Centers also do not appear to be acting in good faith. SaveonSP's argument that a "specialty medication" is not an EHB is not remotely reasonable given that "prescription drugs" is a category of EHBs and all medications within SaveonSP's drug list require a prescription. Additionally, SaveonSP's policies are blatantly inconsistent with HHS's intent as established in the NBPP 2016 and NBPP 2020.⁴⁶ Additionally, as noted, HHS has never

³⁷ 42 C.F.R. 156.122

³⁸ https://www.cms.gov/ccio/resources/files/downloads/essential_health_benefits_bulletin.pdf at p. 3.

³⁹ <https://www.cms.gov/CCIIO/Resources/Files/Downloads/ehb-faq-508.pdf> at p. 4.

⁴⁰ <https://www.cms.gov/CCIIO/Resources/Files/Downloads/ehb-faq-508.pdf> (stating that self-insured and large group plans "are permitted to impose non-dollar limits, consistent with other guidance, on EHB as long as they comply with other applicable statutory provisions.")

⁴¹ <https://www.cms.gov/CCIIO/Resources/Files/Downloads/ehb-faq-508.pdf>

⁴² <https://www.cms.gov/CCIIO/Resources/Files/Downloads/ehb-faq-508.pdf>

⁴³ <https://www.cms.gov/CCIIO/Resources/Files/Downloads/ehb-faq-508.pdf>

⁴⁴ https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs19#ftn8

⁴⁵ https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs19#ftn8

⁴⁶ <https://www.govinfo.gov/content/pkg/FR-2015-02-27/pdf/2015-03751.pdf>;

<https://www.govinfo.gov/content/pkg/FR-2015-02-27/pdf/2015-03751.pdf>

released any guidance permitting such an interpretation of an EHB. Instead, SaveonSP appears to be attempting to exploit a perceived loophole by excluding medications from annual cost-sharing requirements so that plan enrollees will feel pressured to sign up for a copay maximizer program. This is bad faith.

III. The SaveonSP scheme is harmful to patients

SaveonSP's scheme is harmful to patients. This program places patients in an unfair predicament in which they must choose between paying a higher out-of-pocket cost for their medication or entering into a copay maximizer program in which the value of their copay assistance is conveyed to the health plan without counting toward the patient's deductible. Although copay maximizer programs may initially be appealing to patients as they will have no up-front cost for prescriptions, these programs hurt patients in the long run, as patients are still required to meet their annual deductible but without the cost of the prescription medication contributing to that annual amount.

Copay maximizers can also perpetuate health disparities among minority populations. In 2021, a National Hemophilia Foundation survey found that 65 percent of respondents would face difficulties in accessing their treatments if copay assistance programs are not directly contributed to their out-of-pocket expenses.⁴⁷ This study also found that one-third of individuals who were unable to afford their treatments when the copay assistance ran out were people of color.⁴⁸ Maximizer programs like SaveonSP's will only contribute to the perpetuation of healthcare disparities as patients might be able to afford some of their medications but be unable to afford other medications or necessary supplemental care due to remaining high deductibles.⁴⁹

IV. Conclusion

For the reasons provided above, Aimed Alliance and CHLP request that CCIIO confirm our interpretation that Hub Centers, such as SaveonSP violate the ACA and its implementing regulations, and take enforcement action against these companies and/or provide an FAQ confirming our interpretation. We request a virtual meeting to discuss this matter further with you.

Sincerely,

Stacey Worthy
Counsel, Aimed Alliance

Phil Waters
Staff Attorney, The Center for Health Law and
Policy Innovation of Harvard Law School

⁴⁷ <https://www.hemophilia.org/news/covid-19-exacerbates-treatment-affordability-challenges-health-inequities>

⁴⁸ <https://www.hemophilia.org/news/covid-19-exacerbates-treatment-affordability-challenges-health-inequities>

⁴⁹ <https://www.hemophilia.org/news/covid-19-exacerbates-treatment-affordability-challenges-health-inequities>. See also <https://www.mmm-online.com/wp-content/uploads/sites/2/2018/09/AccumulatorAdjustmentProgramsThroughPatientsEyes.pdf>