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Submitted via www.regulations.gov

December 26, 2024

Office of Health Plan Standards and Compliance Assistance
Employee Benefits Security Administration
Room N-5653
U.S. Department of Labor
200 Constitution Avenue NW
Washington, DC 20210

Re: Proposed Rule; Enhancing Coverage of Preventative Services Under the Affordable Care Act; File Code No.: 1210-AC25

Dear Sir or Madam,

The Consumer Healthcare Products Association (CHPA) appreciates the opportunity to submit comments on the Proposed Rule entitled "Enhancing Coverage of Preventative Services under the Affordable Care Act" published by the Departments of Treasury, Labor, and Health and Human Services (collectively, the "Departments") in the Federal Register on October 28, 2024.

For more than 142 years, CHPA has served as a vital advocate for the consumer healthcare products industry. A member-based trade association, CHPA represents the leading manufacturers and marketers of over-the-counter (OTC) medicines, consumer medical devices, and dietary supplements. Our members provide millions of Americans with safe, effective, and affordable therapies to treat and prevent many common ailments and conditions, including oral contraceptives, emergency contraceptives, and contraceptive devices available without a prescription.

Our comments cover three areas:

(1) Maintaining the value that direct consumer access to OTC medicines provides today;

(2) Ensuring that the market-based approaches that are at the core of the OTC medicine system continue to thrive; and

(3) Simplify the pathways and minimize, as much as possible, obstacles for consumers to obtain coverage for OTC contraceptives within the current health system.

(1) Maintain the strong value to consumers and the health care system of direct consumer access to OTC medicines. Access to appropriate medicines without a prescription empowers consumers to take greater control over their health and

provides considerable public health benefits. In 2022, CHPA commissioned a study to estimate the value of OTC medicines to the U.S. healthcare system.[1] The study found that each dollar spent on OTC medications saved the U.S. healthcare system $7.33 in healthcare spending. The overall savings to the U.S. healthcare system totaled $167.1 billion in 2021 compared to alternatives. Savings from drug costs totaled $56.8 billion, which was generated by the lower prices of OTC medicines as compared to more expensive branded or generic prescription medicine alternatives to treat self-managed conditions. The remaining savings came from avoided clinical visits, which represented $110.3 billion of the total annual savings. These savings are the result of consumers making the decision to self-treat with OTCs rather than making a visit to the doctor's office for treatment.

In addition to providing value through cost savings, OTC medications also help reduce the burden on the U.S. healthcare system, ensuring that scarce health care provider resources are reserved for the more serious conditions that cannot be self-treated. The same study estimated that 82 percent of consumers who treat a condition with an OTC medicine would seek professional medical treatment if OTCs were not available in the marketplace. It is clear the U.S. health system would not be able to absorb additional office visits from the millions more of consumers seeking treatment or prescriptions for mild conditions they can self-treat.

Coupled with the growing shortage of primary health care professionals (HCPs) in the U.S., patients would find it much harder to get access to HCPs to receive the prescriptions needed for treatment. While the shortage of HCPs is a nation-wide issue, it is far from uniformly distributed. In fact, counties that have a higher percentage of population residing in the Health Resources & Services Administration (HRSA) defined shortage area geographies tend to have poorer health outcomes. This suggests a treatment gap exists in these areas. It also highlights the need for alternative treatment pathways like expanded access to OTC drugs that leverage the resources available in (often rural) places where traditional medical treatment facilities and practitioners may be absent.[2]

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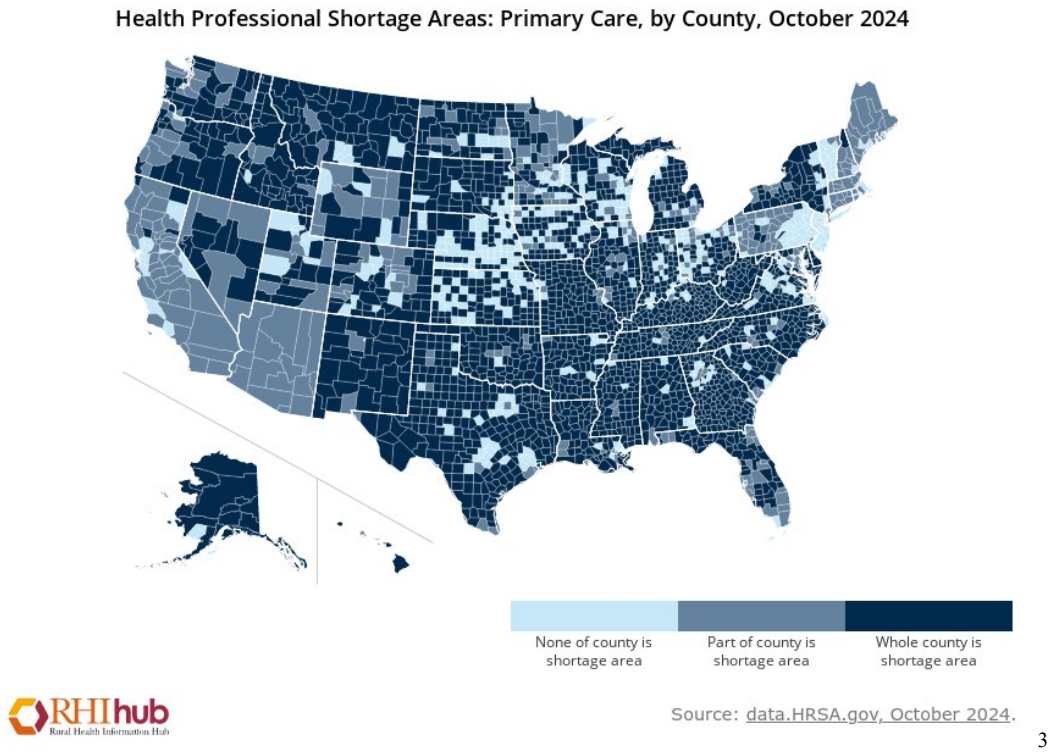
[1] "The Power of OTCs to Provide Consumer Value." IRI and Consumer Healthcare Products Association, November 2022, https://www.chpa.org/sites/default/files/media/docs/2022-11/The-Power-of-OTCs-to-Provide-Consumer-Value.pdf.

[2] Stomberg, C., NERA, *No Doctor, No Problem – the Benefits of Expanding OTC Drug Access*, publication pending. Paper on file with CHPA, December 2024.



[3]

OTC products are now many consumers' first line of defense in treating everyday conditions, such as allergies to heartburn. Since 2001, there have been more than 40 different ingredients or indications switched over from prescription to OTC in categories ranging from chronic conditions, such as allergy and heartburn, to most recently, a progestin-only oral contraceptive. This enables the healthcare system to utilize its limited resources for the diagnosis and treatment of more serious diseases and medical conditions that necessitate the direct involvement of a physician.

(2) Ensure that market-based approaches that are at the core of the OTC medicine system continue to thrive. OTC medicines exist in a highly competitive, market-based environment, with low barriers to entry. When prescription-only medicines are made available as OTC products, a substantially higher number of consumers typically purchase the product compared to when it is only available through prescription. OTC medicines greatly expand access to medicine because they remove barriers (healthcare provider visits, paperwork burdens, and, in some cases, the removal of stigma or embarrassment), reduce costs, and expand available places

[3] "Health Professional Shortage Areas: Primary Care, by County." Rural Health Information Hub. October 2024, https://www.ruralhealthinfo.org/charts/5.

of sale, i.e., multiple types of retail outlets (including mass market, food stores, convenience stores, pharmacies, and e-retailers).

The Food and Drug Administration (FDA) estimated that the transfer from a prescription to a non-prescription drug saved $26.70 per consumer per purchase (within a range of $0 - $53.40) in reduced access costs.[4] Past switches from prescription to OTC status for a drug have repeatedly shown that increased utilization flows from the availability of nonprescription drug alternatives. For instance, Stomberg, *et al*., found utilization increased 27 percent when a new OTC therapy is introduced.[5] Similarly, during a period in which several prescription allergy medications became available as OTC products, the percentage of allergy sufferers using OTC medicines increased from 66 to 75 percent while physician visits for allergies trended downward.[6]

OTC medicines exist in a willingness-to-pay model in which consumers generally pay directly out-of-pocket for the product. Under this model, Americans elected to purchase OTC medicines over 5.6 billion times in 2023.[7] Why? Because, in addition to the medical benefits they provide, OTC medicines provide significant savings in time and access. Further, having a wide range of options allows consumers to select the OTC product of their choice based on individual preferences, product-specific attributes beyond the active pharmaceutical ingredient or medical device action itself, experience, or professional recommendations.

In contrast, acquiring a medicine through the prescription pathway requires a greater number of steps, any one of which adds costs (including time) and can reduce adherence to therapy: visiting a provider, receiving a prescription, receiving any relevant authorization from the insurance plan, finding an in-network pharmacy, and being aware of out-of-pocket costs. This process requires a patient's time commitment and an understanding of each step and relevant information (*e.g*., how to access and understand the plan's benefit design). Conversely, acquiring an OTC product without the involvement of a health insurance plan provides patients with a much simpler and direct route to access.

(3) Simplify the pathways and minimize, as much as possible, the obstacles for consumers to obtain coverage for OTC contraceptives within the current healthcare system. We applaud the intent of the proposed rule to provide Americans with access to zero-cost preventive services without the need to obtain a prescription.

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[4] See, 87 Fed. Reg. 38313, 38325 (June 28, 2022).
[5] Stomberg C., *et al*., *Utilization effects of Rx-OTC switches and implications for future switches*. Health. 2013.
[6] Nielsen for CHPA, *Assessing consumer benefit of allergy Rx-to-OTC switches*. 2017.
[7] "OTC Sales Statistics." Consumer Healthcare Products Association. 2024, https://www.chpa.org/about-consumer-healthcare/research-data/otc-sales-statistics.

There are several factors which, under the currently proposed system, make the experience of obtaining coverage for an OTC contraceptive without a prescription more complicated and potentially confusing to consumers. We ask the Departments to seek ways to reduce these obstacles and make the purchase experience as simple and as close to the current experience for consumers as possible. Below we describe some of these factors and ways to address some of them for the consumer.

In-network

First, for consumers who choose to use their insurance at an in-network pharmacy, instead of making a cash purchase without coverage as done today, the experience will be least changed. The consumer will go to a retail location, pick up the product from the shelf or ask a pharmacist for the product, and check out at the pharmacy with no cost sharing. They could also obtain the product from an online pharmacy with no cost sharing. These are the best-case scenarios, but it requires the consumer to know what product(s) will be covered and that the transaction needs to be completed through a pharmacy (either the pharmacy section within a retail store or on an online pharmacy).

Identifying what products will be covered is likely to be a challenge and create consumer confusion and potential dissatisfaction. For example, health plans may only cover the store brand equivalent of a national brand OTC product, if available, since the requirement to cover all recommended contraceptive drugs or drug-led combination products with no cost sharing unless at least one therapeutic equivalent product is covered at zero cost sharing applies only to drug and drug-led combination products. With respect to drug products, the Departments note that "the FDA does not evaluate therapeutic equivalence for OTC drugs or OTC drug-led combination products and the Orange Book does not categorize such products as a 'therapeutic equivalent' of any other drug or drug-led combination product."[8] Most consumers are not likely to understand these distinctions, and why certain zero-cost sharing OTC contraceptive items may be limited to certain brands while others not. If the chosen product is not covered, the consumer may be directed to exchange the product for an equivalent covered product, assuming the retailer knows which of its OTC products are covered by a particular plan or can look this up for the consumer. This confusion and uncertainty could become a barrier for consumers leading some to leave the store or abandon their online carts. This scenario points to the importance of education of covered individuals and clear and simple plan materials to help members understand what is and is not covered, and the process to be followed for an appeal if their preferred OTC product is not covered.

[8]See, 89 Fed. Reg. at 85770 (October 28, 2024).

Moreover, this may be further complicated by state generic substitution laws and whether such laws apply to the adjudication/processing of OTC product claims, forcing a pharmacist to substitute a store brand or other "generic" OTC product in place of the consumer's selected product. Further, unlike with prescription products, for covered OTC products, there is no ability for a dispensed as written option for consumers to receive the product of their or their physician's choice as no prescription would exist to include a dispensed as written notation. We are unaware of any state-by-state analysis assessing the impact of such laws on the coverage of OTC contraceptive products following the implementation of the proposed rule and it may make sense to take this into consideration before the proposed rule is implemented.

In-Network v. Out-of-Network Coverage of OTC Contraceptive Products

Another scenario likely to cause confusion is if the retail store's pharmacy is in-network, but the front of the same retail store is out-of-network. In that case, for the product to be covered by insurance, the product would have to go through the pharmacy system. This could be especially problematic if the pharmacy has different business hours than the front store since there would be a smaller window of time for consumers to obtain covered OTC contraceptives.

Similarly, a consumer may be able to obtain covered OTC contraceptives through an online pharmacy, but not a retailer's website. As with the physical front of the store, the retailer's website would be unable to process products through insurance. The consumer would have to know which online websites are regarded as online pharmacies and which not and may need to open an account with the online pharmacy, causing a delay in obtaining the product.

The adjudication process could also be another barrier to access. Currently, OTCs that are covered by insurance must be entered into the same system as prescription drugs. While the framework may be similar, there are many more fields that need to be populated to fill a prescription drug compared to an OTC item. Since the system is built for prescription drugs, this may cause some claims to be falsely rejected, for example if a prescription number or NPI is not included. While the pharmacist should be given instructions on how to override the system in these instances, there may be situations where a covered OTC is rejected or the consumer has to come back for the product, causing a delay and barrier to access. If the pharmacist is unable to override the system and the covered product is rejected, the consumer would have to pay out-of-pocket and submit a claim for reimbursement on their own.

Another complication is that in twenty-seven states and the District of Columbia pharmacists are required to complete a screening tool before they can dispense a hormonal birth control, and nineteen states and the District of Columbia

require the pharmacist to provide contraceptive counseling.[9] This may lead to confusion at the pharmacy as to whether the pharmacist needs to complete a screening or provide contraceptive counseling for OTC birth control. If the pharmacist does have to complete a screening or provide counseling for OTC products, this may deter some consumers from using their insurance. Some states have started to exclude OTC hormonal birth control from the screening and/or counseling. For example, California recently introduced a bill to simplify access for Medi-Cal recipients by removing the screening tool for OTC birth control.[10] The changing requirements of state law are another area of uncertainty and potential confusion.

If a consumer obtains OTC oral contraceptives from an out-of-network outlet, either a retail store or online pharmacy, they will have to pay for the products up front and submit a claim. Though they would likely not be reimbursed since they choose to purchase the product at an out-of-network retailer. However, there may be instances where a consumer may need to purchase the product out-of-network due to no in-network pharmacy nearby or medication not stocked at in-network pharmacy.

In the case of consumers with no/open network coverage, they could go to either a retail store or online to purchase OTC oral contraceptives and pay for it up front then submit a claim. In contrast to the out-of-network scenario, they should get fully or partially reimbursed depending on the item they choose and their plan's coverage.

Reimbursement Mechanisms

Possible alternatives in lieu of the post purchase reimbursement process is if the plans provided a debit card, smartphone application, or QR code. Similar to the Medicare Advantage plans that may provide debit cards to purchase supplemental benefits, the debit cards would need to be electronically linked to plan covered benefits through a real-time identification mechanism to verify eligibility of plan coverage at point-of-sale.[11] This would ensure that the debit card would only be used towards plan-covered items. Also, smartphone applications or QR codes could aid in expediting the claims process by allowing the consumer to instantly upload the receipt and submit the claim for reimbursement. With either alternative, education for the consumer would need to be provided on how to use debit cards, smartphone applications, or QR codes, in addition, to providing guidance on which products are

[9] "Pharmacist-Prescribed Contraceptives." Guttmacher. 8 November 2024, https://www.guttmacher.org/state-policy/explore/pharmacist-prescribed-contraceptives.
[10] O'Connell-Domenech, Alejandra. "California bill would ease access to over-the-counter birth control pills." The Hill. 3 December 2024, https://thehill.com/policy/healthcare/5020366-california-bill-over-the-counter-birth-control/.
[11] See, 89 Fed. Reg. at 99387 (December 10, 2024).

covered. We encourage the Departments to work with all stakeholders to develop consumer-friendly reimbursement methods and to ensure that members understand what their options are and how they work. In addition, protections should be implemented to ensure that if a particular method is unavailable for any reason (e.g., a debit card network is down), there are alternative methods available for members to obtain coverage short of paying out-of-pocket and seeking reimbursement after the fact.

Privacy Considerations

Another scenario is where a consumer does not have insurance or elects not to use insurance and purchases OTC contraceptives either online or in a retail store without reimbursement. Many individuals are more concerned about sharing their contraceptive information with their health plans than with the need for privacy when purchasing OTC items. This may be because in the case of health plans, OTC information is clearly linked to the plan member in the health plan records, whereas today there is no necessary connection between the purchaser of a nonprescription item at front of store and a plan or healthcare provider. In contrast, if purchased through a plan, there is the potential that the OTC information held by the health plan could be viewed by a family member who manages the family's health benefits. It is for this reason that it is not uncommon for individuals who have health coverage to nevertheless choose to pay out-of-pocket for contraceptive items so that the information is not shared with their health plans.

The Departments ask about privacy concerns that would arise if covered OTC items are obtained at non-pharmacy retail outlets or the front-end of stores with pharmacies that are not treated as health care providers. As the Departments note, front stores of pharmacies and other retail outlets often lack the safeguards to protect patient privacy that are required to be implemented by pharmacies and other health care providers subject to the Health Insurance Portability and Accountability Act (HIPAA). These safeguards include physical safeguards, such as separate counters at which patients may obtain the covered items with relative privacy, as well as administrative and technical safeguards, such as training for staff and access controls to limit access to the individual's information.

We share these concerns, which we agree are heightened due to the especially personal and sensitive nature of contraceptive information, and reproductive health care information generally. While individuals may be more willing to utilize their health coverage to obtain OTC contraceptives at zero cost sharing when a prescription is no longer required, they will still need to weigh the privacy risks associated with sharing this information with their health plan. We believe this is likely to remain the

main privacy concern for individuals as the privacy aspects of the front store purchasing experience will be little changed.

In addition, as HHS notes, the legal landscape for reproductive health care services is changing rapidly following the U.S. Supreme Court decision in *Dobbs v. Jackson Women's Health Organization* (Dobbs),[12] which has in turn triggered new state and federal laws affecting reproductive health and reproductive health information privacy.[13] While these changes pose new challenges for health care providers and others facilitating reproductive health care, the trend towards greater privacy protections for reproductive health information and personal information generally is a welcome development for consumers. Since California passed the first comprehensive privacy law in 2018, many other states have followed suit. Today there are 20 states that have passed comprehensive data protection laws, and this number is likely to increase in 2025.[14] This means that even personal information held by retail outlets and front stores that is not subject to HIPAA protections is increasingly likely to be protected by state privacy laws. These laws generally place limits on how personal information collected by businesses may be used and disclosed, and usually also give consumers new rights with respect to this information, such as the right to request that it be deleted.

While these factors suggest that the lack of HIPAA protections for OTC information at retail outlets and front stores may not be as significant an issue as might first appear, we nevertheless encourage the Departments to work with all stakeholders to determine what additional privacy measures could be implemented at point-of-sale locations without unduly burdening retail outlets, front stores or other locations at which such OTC contraceptive items are purchased.

Coverage Limits

Another set of issues raised by the proposed rule are reasonable purchase limits and fraud, which are interconnected. We agree with the Departments that a 30-day limit on oral contraceptives may not be reasonable, given their daily regimen use. The

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[12] See, 597 U.S. 215 (2022).

[13] See, for example, the final rule to protect the privacy of reproductive health care information published in the Federal Register on April 26, 2024 (82 Fed. Reg. 32976) by the Department of Health and Human Services, which has since been challenged in State of Texas v. Becerra.

[14] As of September 2024, 20 states had passed comprehensive state privacy laws. See https://pro.bloomberglaw.com/insights/privacy/state-privacy-legislation-tracker/ and https://www.mayerbrown.com/en/insights/publications/2024/10/the-evolving-us-privacy-landscape-essential-insights-for-2024.

same rationale does not apply to emergency contraception which, as the description states, is for episodic emergencies. OTC condoms acquired through a woman's health plan coverage could fall between the daily and episodic emergency extremes. As a cash market for these products will remain, a fraud concern is that absent reasonable limits, the acquiring party could resell these products through a third-party website (or a black market). This is already a challenging issue with OTC medicines and OTC devices, where both counterfeit goods or diversion (including organized retail theft) are not uncommon.[15] In light of this, we support reasonable coverage limits based on clinical guidelines and the nature of the product.

Beyond the existing challenges with fraud through diversion, absent reasonable limits on purchases, there is a risk that a handful of consumers could deplete in store stock of products available on shelf. For example, many large stores only keep a handful of units of OTC emergency contraception on shelf each day (9-12 units per store at a large, fully stocked store) and, at the currently suggested per purchase limit of 3 units per trip (for a product only indicated for the use of a single unit per birth control failure), if 3 or 4 consumers came into the store to utilize the proposed benefit, it is very likely any additional consumers entering the store that day would find the product out of stock and be forced to either travel to another store or forgo their purchase although for a product that needs to be taken in a timely manner.[16] In this case, the proposed rule could lead to an actual decrease in consumer access to a product, rather than an increase in access.

The risks noted above for consumer fraud through product diversion or a decrease in on shelf availability, absent reasonable purchase limits, are further compounded by the broad scope of the proposed rule. Nothing in the proposed rule suggests that coverage of OTC contraceptive products is limited to those of reproductive age or ability. By their very nature as a self-treatment option, OTC products, unlike prescription products, are not limited to purchase by consumers who have an actual medically determined need for the product. This means that consumers with bad intentions and no need for the product would still be covered by the proposed rule and able to acquire the product at no cost for resale at the expense of not only the insurers (and employers and the government in turn), but also at the expense of consumers who have actual need for the product if those diverted units are no longer available on shelf.

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[15] The Office of the U.S. Trade Representative requested comments on the inter-related issues of counterfeiting and piracy earlier this year, on which CHPA submitted comments. See 2024 Review of Notorious Markets for Counterfeiting and Piracy: Office of the United States Trade Representative (USTR) Comment Request. [Docket Number USTR-2024-0013].

[16] See, 89 Fed. Reg. at 85768 (October 28, 2024).

Conclusion

We applaud the intentions of the proposed rule to expand access to needed products for contraception. We note, however, that the proposed rule raises significant challenges that would need to be addressed, as discussed throughout our comments.

We appreciate the opportunity to submit these comments and are available for further information.

Respectfully Submitted,

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