December 4, 2023

The Honorable Janet Yellen
Secretary of the Treasury
1500 Pennsylvania Avenue, NW
Washington, DC 20220

The Honorable Julie Su
Acting Secretary of Labor
200 Constitution Avenue, NW
Washington, DC 20210

The Honorable Xavier Becerra
Secretary of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Submitted electronically via http://www.regulations.gov

RE: Over-the-Counter Preventive Items and Services Available Without a Prescription — AHIP Comments

Dear Secretaries Yellen, Su, and Becerra:

Every American deserves access to affordable, high-quality coverage and care. As the national association whose members provide health care coverage, services, and solutions to hundreds of millions of Americans every day, AHIP appreciates the opportunity to comment on the request for information (RFI) on over-the-counter (OTC) preventive items and services available without a prescription by a health care provider.

We support the Tri-Departments’ interest in increasing access to OTC preventive health care options, starting with OTC contraception, with appropriate guardrails. Affordable preventive items and health care services promote health and well-being and prevent disease for patients and consumers; health insurance providers already process 94% of commercial contraceptive medication and device claims without any patient cost sharing. In our comments, we emphasize the need for health insurance providers to promote access and affordability by directing them to preferred retail settings. We provide recommendations on ensuring implementation places minimal burdens on consumers, providers, pharmacists, and health insurance providers. We also discuss the benefits and challenges with several approaches to operationalizing OTC coverage.

1 AHIP analysis of National Drug Codes (NDC) of medications and devices used for contraception, using data from the Department of Health and Human Services Office of Population Affairs, and pharmacy claims related to contraception extracted from the Merative TM MarketScan® Research Commercial Database for the period from January 1, 2021, to December 31, 2021. Claims with incomplete or missing payment information have been excluded from the analysis.
As a first step, we encourage the Tri-Departments to allow for maximum flexibility in how any new requirements are implemented. To prepare for this potential new requirement, numerous stakeholders must take critical operational steps that will require lead time. Clear communications and plenty of lead time for implementation are of utmost importance. The following strategies and considerations build on lessons learned from requirements for coverage of COVID-19 tests and existing state requirements, potential applicable options include:

- To leverage the existing pharmacy and retail networks and infrastructure, OTC products can be processed through pharmacy departments to process claims with no cost to consumers at the point of sale (POS).
- When processing OTC products, with or without a prescription, health insurance providers should only be required to cover products without cost sharing when they are accessed via in-network providers, pharmacies, or other preferred retail settings.
- Health insurance providers can establish processes for direct reimbursement to consumers after they have purchased preventive products if they pay out of pocket because they prefer not to process the items via their insurance or they do not have insurance.
- To build on existing models that are used in public programs, OTC products could be purchased with a pre-loaded “debit card-like” approach that shields consumers from costs at the POS.

Additionally, we recommend that the Tri-Departments:

- Designate only those OTC preventive products and services recommended by the United States Preventive Services Task Force (USPSTF) with “A” and “B” recommendations, HRSA, ACIP, or Bright Futures, in accordance with Public Health Service Act section 2713 jurisdiction, to be required for coverage without cost sharing or prescription, with a phased approach starting with OTC contraception.
- Establish guardrails to ensure appropriate use, including encouraging the use of generics to promote affordability.
- Allow all stakeholders including issuers and employers adequate time to implement new requirements (e.g., at least the plan year beginning one year after the final rule).

Thank you for the opportunity to provide feedback on this RFI regarding potential access to OTC preventive items and services. We support the Tri-Department’s efforts to expand access to and use of preventive care, and we align with the Administration in seeking to keep care affordable and equitable. We stand ready to work with the Tri-Departments in meeting this shared goal and look forward to continued partnership. We welcome the opportunity to discuss our comments.

Sincerely,

Jeanette Thornton
Executive Vice President
Attachment
AHIP Detailed Comments

Understanding Access to and Use of OTC Preventive Products
The RFI presents questions about current access to and use of preventive products including how plans currently provide coverage of OTC products, measures of use, and communications considerations.

**OTC Coverage for Preventive Products**
The Affordable Care Act (ACA) requires health insurance providers to cover preventive products and services recommended by the USPSTF with an “A” or “B” recommendation, the Health Resources and Services Administration (HRSA), Advisory Committee on Immunization Practices (ACIP), and pediatric Bright Futures Periodicity Schedule when prescribed. Current interpretations of the Public Health Services Act (PHS) section 2713 have indicated that coverage can be required only when products are prescribed.²³ AHIP recommends the Tri-Departments engage key stakeholders, including health insurance providers, to better understand the impacts that changes to coverage of preventive items and services OTC may have on utilization, costs, workforce, consumers, and other potential impacts. We recommend the Tri-Departments issue further guidance through notice and comment rulemaking to allow the public to weigh in on the new proposed interpretation of the statute.

We recommend future coverage requirements for OTC preventive services only apply to preventive products and services recommended by USPSTF with a “A” or “B” recommendation, HRSA, ACIP, or Bright Futures, as addressed in Section 2713. To best operationalize new requirements for OTC coverage, we recommend that the Tri-Departments consider a phased approach starting with OTC contraception. This will give stakeholders time to implement changes and to communicate with patients about the changes, so they know what to expect.

We also encourage the Tri-Departments to consider applying coverage requirements without cost sharing to generic products, where such a product may be available. Health plans must maintain the ability to design benefits to fit the needs of their members, and instances where both a generic and brand product are available, insurance providers should retain the ability to apply no-cost sharing to a preferred option to promote affordability.

It is important to note that Health Savings Accounts (HSA) and Flexible Spending Accounts (FSA) currently fill a critical role to support affordable access to non-prescribed OTC products and allow millions of Americans to access OTC products with pre-tax dollars. For example, HSA and FSA dollars can be used to cover OTC smoking cessation and breastfeeding supplies, when

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they may not be covered by a prescription. Further conversations and guidance will need to consider any downstream effects on current health plans that offer HSA and FSA products.

Coverage of OTC Contraception
Access to contraception can have a critical impact on women’s health and well-being. The ACA requires that plans cover at least one option from each category of Food and Drug Administration (FDA)-approved methods of contraception without cost sharing. Health insurance providers offer access without cost sharing to many FDA-approved contraceptive options, consistent with and beyond the requirements of federal law, and many insurance providers report covering dozens of formulations of contraception. Health plans must also offer an easy and fast way for patients to access the contraception option they may need. Studies have shown that 65 percent of women of reproductive age are currently using contraception⁴, and that the progestin-only “mini-pill” – the same clinical category as Opill - is one of the most common methods of contraception used by women and is currently available through the pharmacy benefit with a prescription and with no cost sharing.⁵

Health insurance providers play a critical role in balancing the cost of care while promoting access to high-quality, necessary care. Health insurance providers’ clinical care teams, staffed by pharmacists and physicians, develop coverage policies to ensure women receive care that is safe and effective. Insurance providers also negotiate prices with pharmaceutical manufacturers as a way to offer affordable products to employers and to individuals purchasing their own coverage. To ensure safe and affordable care for women, federal regulations allow the use of medical management to promote affordability and efficient delivery of care.⁶ The availability of OTC contraception without a prescription could shift the clinical landscape for women’s health and reproductive care. Recognizing the importance of access to OTC contraception and other preventive items, we encourage the Tri-Departments and other stakeholders to promote patient education regarding the important preventive services they may need, counseling related to preventive services and information on potential risk factors and side effects patients should be aware of. It is also important to note that patients should be made aware of other important clinical care and screenings that they should receive from a clinician.

State Coverage for Preventive Products
There are state requirements for health insurers to cover OTC contraception, as well as other items at the state level, where health insurance providers in those states adhere to those requirements. This includes, for example, female and male condoms or sponges to be obtained by consumers without cost sharing. To date, 13 states have specific rules on coverage of OTC contraception, and six of those states require plans to cover at least some OTC methods without a

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⁵ [https://www.healthcare.gov/coverage/birth-control-benefits/](https://www.healthcare.gov/coverage/birth-control-benefits/)
⁶ (45 C.F.R. 147.130)
prescription. Additionally, 16 states have some laws or regulations that require plans to cover OTC smoking cessation treatments.

In the states that offer OTC coverage without cost sharing, there are several ways these items are processed. In some states, post-purchase reimbursement is available. This can be challenging for consumers, health plans, and retailers. In these situations, for example, a consumer buys the product from a retailer and submits documentation – often a form requesting reimbursement and purchase receipt – to receive reimbursement from the health plan. In other states without existing processes like these, plans may encourage consumers to obtain these preventive products at no up-front patient cost by visiting the pharmacy counter, allowing the claim for the OTC product to be processed in the same manner as a prescription and directly billed to the insurance provider. In these cases, in-network pharmacies can process no-cost purchases at the POS. In some states, pharmacies use their National Provider Identifier (NPI) to process an OTC purchase at the pharmacy counter and other states have established standing orders to allow for immediate processing at the POS. Additional considerations for these approaches are provided in comments about implementation.

There are some examples from states that indicate possible options for providing coverage or reimbursement for OTC products. Based on state experience, however, there may be lessons learned but not necessarily easy solutions. Insurance providers should have the flexibility to implement any new policies to meet the needs of their members.

**Benefits of Existing Claims Infrastructure**

The current pharmacy claims infrastructure can reduce consumer financial burden, facilitate clinical care coordination, allow providers to track which medications a person is taking, flag any possible drug interactions with other prescribed medications, ensure consumers are aware of side effects, and help prevent unnecessary use. When OTC products are processed through the traditional pharmacy claims process, they can be immediately available to a person’s care team or insurance provider. This can help providers with care coordination including whether a patient’s medications could have negative interactions or other clinical risks.

AHIP believes it is important to leverage the existing pharmacy claims infrastructure to provide the lowest up-front cost to consumers electing OTC preventive items as one option. This approach would provide insight into how often these items are purchased and can reduce overall health care spending by helping identify possible waste, such as when a patient switches to a new form of OTC contraception before completing the previous course of OTC contraception, if they do so through the pharmacy claims infrastructure. Identifying possible waste through standard pharmacy claims procedures can inform the development and use of appropriate medical

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7 https://www.kff.org/other/state-indicator/state-requirements-for-insurance-coverage-of-contraceptives/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22,%22%7D

8 https://www.cdc.gov/tobacco/quit_smoking/cessation/coverage/index.htm
management approaches to contain overall health care spending while ensuring appropriate access.

While waste is often mentioned with fraud and abuse, waste considerations should be differentiated, as the intentions are not malicious or deceptive – even without bad intentions, OTC products can lead to wasteful expense. For example, some states with mandatory coverage requirements for contraception without a prescription require that health insurance providers cover several months’ supply at a time – in some cases, up to 12 months. Health insurance providers are concerned that 12 months’ supply could easily lead to waste, particularly for new users. A person may experience side effects, have difficulty with adherence, prefer another form of contraception (or none), or other factors that could lead to a person not using the full supply, thus making the remainder of the supply wasted product. While we agree that individuals using preventive services may require more than a one-month supply or other short-term option, policymakers should consider that allowing longer term supply may result in waste.

To combat other opportunities for fraud, waste, or abuse, insurance providers should be able to establish guardrails to prevent multiple purchases of similar products from multiple pharmacies or retailers in order to discourage diversion. The current claims systems help prevent this kind of abuse by tracking where and when people receive access to products.

Communications Channels
It will be important that all stakeholders have clear information on how the process will work. This includes informing consumers, providers, pharmacies, and health insurance providers about the new requirements and allowing an appropriate transition time before any new requirements go into place. Health insurance providers will play an important role in communicating with providers and patients including disseminating information about preferred retail settings where their members can most easily access care and other specific information that may be most relevant. To do so, health insurance providers will need clear and specific guidance, along with adequate time to update plan materials, update internal systems and processes, coordinate with vendors, and streamline with existing communications and deadlines.

Retailers and providers also have a critical communications role to fill to inform patients about OTC coverage. Retailers must include consumer-facing messaging specific to the processes required in their store to process coverage, which may differ by retailer. Pharmacists can play a critical role in communicating the operational and clinical considerations to patients, and they may need education and training on how to counsel patients interested in obtaining OTC products without a prescription or cost sharing. Doctors and other providers will also be a trusted source of information for their patients about how and when to seek preventive services OTC without a prescription.

In some states where products are available without a prescription, health plans inform their members about product availability, which pharmacies or retailers are considered in-network,
and provide instructions on how to submit a claim for reimbursement, where applicable. In another example of a state with coverage requirements, coverage and processing information is communicated through the pharmacy and delivered to consumers by the pharmacist or other pharmacy staff.

**Recommendations:**

- The Tri-Departments should designate only those OTC preventive products and services recommended by USPSTF with “A” and “B” recommendations, HRSA, ACIP, or Bright Futures, in accordance with PHS Act section 2713 jurisdiction, to be required for coverage without cost sharing or prescription, with a phased approach starting with OTC contraception.
- The Tri-Departments should apply lessons learned from stakeholder experience with existing state coverage and cost sharing requirements to make any policy changes as seamless as possible for consumers.
- The Tri-Departments should establish guardrails to ensure appropriate use and to reduce fraud, waste, and abuse and allow for medical management.
- The Tri-Departments should enable drug manufacturers, retailers, pharmacy departments, doctors and other providers, and health insurance providers to clearly communicate coverage, costs, and processes to consumers to reduce confusion and allow plenty of time for stakeholders to communicate and operationalize any new requirements.

**Implementation Considerations and Challenges**

Patients purchase OTC preventive products through many channels. Therefore, the solution to OTC preventative care coverage should include a wide array of options for patient access. These options should include, but not be limited to, traditional pharmacy access, post-purchase reimbursement, online purchasing with shipment portals or retail pick-up, “debit card-like” methods issued by plans, and other options that meet the minimum standards determined by further guidance. A requirement for plans and issuers to cover OTC preventive products without a prescription or patient cost sharing would create operational challenges and will have a broad impact on several stakeholders, including patients, health insurance providers, employers, retailers, and pharmacies.

The RFI includes questions about access, privacy, POS costs, administrative considerations, and concerns about fraud, waste, and abuse. Changes to requirements would also impact tele- and mail order pharmacies, and existing contracts between health insurance providers, pharmacy benefit managers (PBM), network pharmacies, providers, and information technology (IT) systems. AHIP encourages the Tri-Departments to allow for flexibility in how any requirements are designed and implemented to encourage innovative solutions that meet consumers’ varied needs.
Leveraging Existing Retail and Pharmacy Networks and Claims Infrastructure

It is important to leverage the existing retail and pharmacy networks and the existing claims infrastructure, which is a robust, well-developed system that allows patients to access prescribed medications at specified cost sharing amounts across many locations. Leveraging the existing pharmacy and retail network and claims infrastructure, particularly coverage at the pharmacy counter, is a good option for providing access to OTC products without cost sharing.

The existing pharmacy claims infrastructure relies upon established networks that allow health insurance providers to negotiate reimbursement rates for covered items and services and promote affordability for consumers and purchasers. Encouraging the use of in-network providers, pharmacies or retail settings to access OTC products without cost sharing is consistent with existing coverage requirements for preventive products and services. Health insurance providers are required to maintain network adequacy with respect to pharmacies, thereby ensuring members have access to OTC products when processed at the pharmacy counter.

When processing OTC products, with or without a prescription, health insurance providers should only be required to cover products without cost sharing when they are accessed via in-network providers or pharmacies or other preferred retail settings (as we discuss below), in alignment with the PHS Act, where contracts have been established to keep care affordable. Absent this network requirement, a coverage mandate for preventive OTC products may encourage some retail providers and/or manufacturers to charge excessive markups on covered OTC products, resulting in higher health care costs. This is consistent with the Tri-Departments reasoning for coverage of preventive services in the July 2010 interim final rule, which found that “permitting cost sharing for recommended preventive services provided by out-of-network providers is the appropriate option to preserve choice of providers for individuals, while avoiding potentially larger increases in costs and transfers as well as potentially lower quality care.”

Health insurance providers also frequently use tele-pharmacy and mail-order or online pharmacy options for their members, designated as in-network options. Coverage requirements for COVID-19 tests allowed insurance providers to designate at least one mail-order pharmacy as an “in network” option; similar designations may be appropriate for OTC contraception. These options could help expand access to OTC products, both when consulting with a provider via a telehealth option or when ordered via a designated preferred access channel. These channels would also expand access to products 24/7, outside of traditional pharmacy hours and to alleviate any geographic burdens.

Preferred Retail Networks and Direct Post-Purchase Reimbursement

We recognize that pharmacy counter processing may limit access to OTC products to locations with pharmacies or other retail settings and to traditional business hours. However, some preventive products may also be available in other retail settings. Therefore, another option

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health insurance plans should be allowed to consider is establishing preferred retail channels with direct-to-consumer access.

During the COVID-19 PHE, health insurance providers used preferred retailers and direct-to-consumer access channels to provide access to COVID-19 tests at no cost. These arrangements helped ensure access and permitted tools to maintain affordability and to prevent fraud, waste, and abuse. For example, insurance providers identified preferred retailers to create options where consumers could purchase OTC tests, leveraging their pharmacy networks and direct-to-consumer shipping programs. Under this program, consumers could access COVID-19 tests from preferred access channels at no cost or be reimbursed if they purchased OTC COVID-19 tests from non-preferred pharmacies or other retailers; however, insurance providers were permitted to cap reimbursement when accessed via non-preferred retailers (e.g., price capped at $12 per test if out of network).\textsuperscript{10} Based on this experience, plans should be allowed to encourage patients to seek access to covered OTC preventive items at preferred retailers, such as by offering lower reimbursement on items from out of network sites.

Establishing preferred retailers and encouraging in-network purchases is preferable because it lessens equity challenges and administrative burden and costs. Out-of-network purchases that require post-purchase reimbursement would require patients to bear the up-front costs for the products when they are purchased and wait for reimbursement from their health plan, thereby potentially creating financial barriers, especially for underserved communities whom these efforts are trying to reach. Additionally, to keep overall costs lower for patients, health insurance providers should be able to maintain the tools and flexibility to steer patients toward lower cost generic options when available.

These flexibilities are important to consider, for instance, when OTC contraception becomes available, a person would have to pay the list price for the OTC pill when purchased out-of-network, reported to be as much as $50\textsuperscript{11}, depending on retailer markup, then submit a form for reimbursement to their health plan and wait to be reimbursed. In this circumstance, the individual still must use their health insurance information for processing – albeit via submitted information to their health plan after their purchase rather than at a pharmacy counter. Allowing plans to encourage the purchase of a generic product in this case could also help reduce the initial up-front costs for patients. As competition increases, including generic options, health insurers may be able to negotiate lower prices that will benefit patients and consumers.

As learned during the COVID-19 pandemic, post-purchase reimbursement is also burdensome from an administrative perspective, for consumers and health insurance providers alike. Even in states where coverage of OTC products is required, health insurance providers report a low number of submissions for reimbursement – the process of submitting paperwork and receipts is simply too burdensome for those who would benefit from the OTC products. And on the


\footnotesize{\textsuperscript{11} https://kffhealthnews.org/news/article/over-the-counter-birth-control-pill-cost-insurance-coverage-opill-perrigo/}
insurance side, any submission needs to be manually reviewed and processed, adding significant administrative burden.

For most consumers, accessing OTC preventive products in-network will be the preferred option, given equity issues, costs, and administrative burden. Health insurance providers should be allowed to encourage in-network use and should retain the flexibility to direct consumers towards the preferred access channels. However, some consumers may still choose to purchase preventive services from non-preferred retailers or those without pharmacy processing capabilities. Direct post-purchase reimbursement, while potentially burdensome to consumers, pharmacies and health insurance providers, should be considered as an option, as was demonstrated by the COVID-19 tests. If further guidance is issued, health insurance providers will work to make forms accessible and as streamlined as possible in an effort to mitigate some of the administrative burden and reimbursement will occur as quickly as possible.

Additionally, despite guardrails for preferred retailers, concerns remain around fraud, waste, and abuse - as was seen with COVID-19 test coverage. Network requirements protected against bulk-purchase with the intention of resale and automatic refills or co-prescribing of clinically unnecessary products. Other requirements, such as the requirement for health insurance providers to cover shipping and taxes when providing mail-order access to COVID-19 tests, for example, led to some pharmacies proactively mailing members OTC tests to consumers monthly through auto-shipments, creating waste when tests were not used as frequently as they were distributed.

Implementing direct reimbursement for OTC COVID-19 tests presented its own operational challenges that may apply to other OTC products and services. With COVID-19 tests, member-submitted claims were often not submitted with the appropriate details (e.g., billing codes, documentation, and receipts). It was challenging for plans to determine how to reimburse consumers without these details. Similar challenges could arise for smoking cessation products, for example, where there are several forms/methods of OTC smoking cessation products available and health plans should have the flexibility to determine if different parameters may be considered for when one product may be preferred over another. OTC contraception could also prove challenging in that it may be available in pharmacies, convenience stores, via online retailers, and other retailers, which could create inconsistencies in the way codes are applied.

“Debit Card-Like” Methods for Pre-Purchase Payment

While the current pharmacy network and claims infrastructure generally requires patients to have covered items or services billed to the insurer at the pharmacy counter POS, it may be possible to allow patients to obtain OTC products at both pharmacy settings and non-pharmacy POS locations using “debit card-like methods” or other mechanisms.

Some AHIP members that offer Medicare Advantage and Medicaid products have experience in providing benefits via debit card-like methods. These tools function similarly to debit cards for
HSAs or FSAs. A set amount is available for use on a debit card for only IRS-approved items. Such an arrangement for OTC products would avoid the need for upfront out-of-pocket payments for consumers and the need to process a claim for the product but would require new policies or procedures along with guardrails. For example, a debit card could only be used for one purchase of a specified product per month.

In Medicare Advantage plans, enrollees typically get an allowance to spend on approved OTC items. Some plans use a debit card for the enrollee to access the benefit by using the card at approved retailers on approved items, some plans provide a regular allowance on the card, some determine amounts through instant pre-authorizations for certain products, and others use a catalog of allowed items and require the enrollee to order through the catalog. Health insurance providers determine how best to devise this type of benefit; this flexibility has allowed health plans to create more robust and creative options for their members. Some state Medicaid programs offer a similar benefit with pre-loaded cards, with funds available to purchase designated products, where any unused funds can be issued back to the insurer.

This option may not work for everyone, as there may be inconsistencies in availability of these programs across different types of insurance products (e.g., Medicare, Medicaid, commercial insurance). Operationalizing the debit card option could be challenging in the commercial market. In the Medicare Advantage example, members have the option to purchase qualified OTC items that are for more general use and do not carry safety risks or contraindications, like compression socks or contact lens solution, rather than preventive items and services such as tobacco cessation or contraception products where use is dependent on the relevant population. Because further analysis is required to understand overall costs for all preventive products, we recommend plans have the option to test this type of arrangement for a limited number of preventive products and to limit use to in-network providers or preferred retail channels. Providing ample lead time will allow health plans to test these options with specific products to evaluate the viability of this option.

Regardless of where patients access covered OTC products, insurance providers must have the flexibility to direct members to in-network pharmacies or preferred retailers when purchasing OTC products without a prescription and without cost sharing.

**Coding Considerations**
Processing OTC products through the pharmacy department could leverage existing coding infrastructure. Accurate medical coding helps health insurance plans process claims, determine appropriate reimbursement, and analyze utilization and clinical data. Accurate medical coding ensures that patients, providers, and insurers receive the correct payments and information for health care services rendered.

The RFI asks about how patients access OTC products without a prescription. There may be some operational complications given existing systems, and who may be able to answer
consumer questions, should they arise. For example, a pharmacy or other retail location may stock aspirin on the store shelf and behind the pharmacy counter – causing possible confusion about how to process a product. Using coding mechanisms allows a product to be processed through the pharmacy department.

Some pharmacy and PBM benefits software systems may only be set up to process prescribed products. To alleviate this issue, we encourage the Tri-Departments to work with states to allow the pharmacist or other appropriate provider to prescribe OTC products at the POS using their pharmacy NPI number or create a standing order for certain preventive items or products, both of which have been enacted in some states. This approach would allow for existing systems to be used, allow for insurance processing, and make it easy for consumers. The Administration could create systems that include a list of preventive products, similar to HSA/FSA eligibility, which could be processed with a specific pharmacy template without the need for a specific prescriber and incorporate these products into national databases used for processing pharmacy claims, such as Medispan and First Databank.

Other Considerations
The Tri-Departments requested information about how contracts between health insurance providers and PBMs, network pharmacies, and providers may be impacted. These contracting decisions are made at the individual plan level. We recommend that the Administration consider potential cost implications for plans consumers and purchasers.

As some pharmacy systems do not currently have the capacity to bill insurance companies without a prescription, stakeholders will need plenty of time to ensure as smooth a transition as possible. New coverage mandates should not take effect until at least the plan year beginning one year following the effective date of a final rule, in alignment with coverage requirements for new recommendations under Section 2713 of the PHS Act.

Recommendations:
• Consistent with long-standing Tri-Department guidance, cost sharing for covered OTC preventive items should only be required to be waived at in-network access points, which may include pharmacies, other retail locations, and mail-order or other remote access.
• Tri-Department guidance should allow health insurance providers to encourage the use of generic OTC products when available and appropriate to promote affordability.
• The Tri-Departments should allow health insurance providers to be able to encourage patients to seek preventive services OTC at in-network access points including retail, mail-order and tele-pharmacy to promote affordability.
• The Tri-Departments should allow stakeholders appropriate time to implement any new requirements to allow for appropriate communications and to get the needed systems in place (e.g., at least the plan year beginning one year after the final rule).
Ensuring Equitable Access
We appreciate that the RFI asks about health equity and how certain populations may be affected by new coverage requirements for OTC preventive products. Health insurance providers are committed to ensuring equitable and affordable access to care, including high-value preventive services for all populations. Creating coverage of preventive care OTC may reduce barriers to care and access to some services at the pharmacy or other retail settings, including reducing travel-related issues and thereby promoting equity, particularly for those who may be in rural or other underserved areas.

Pharmacy access to OTC products provides an additional benefit because pharmacy access is widespread throughout the U.S. – data shows that nearly 90% of Americans live within 5 miles of a community pharmacy. For many, pharmacies are the primary access point to the health care system, especially for those living in rural and underserved communities. However, pharmacies may have workforce challenges and there may be increased wait times for people to get their prescriptions and various vaccines. Depending on the volume of consumers who will now interact with pharmacists and pharmacy staff regarding their OTC products, this may exacerbate an already challenging situation for some pharmacy locations.

Health insurance providers support the use of mail-order options to further extend access to OTC preventive products when they are needed outside of traditional pharmacy hours, given provider shortages, or where there may be geographic or other barriers experienced by consumers seeking access. While we address access to tele- and mail-order pharmacy services in our recommendations for implementation, we also recognize the importance of these services in providing equitable access to preventive products, especially in rural or underserved areas.

We caution the Tri-Departments that making coverage required without a prescription does not necessarily increase equitable and affordable access to OTC preventive products. To keep costs to consumers low should they be utilizing a post-purchase reimbursement option, OTC products must be affordable.

Economic/Socioeconomic Impact
The RFI includes questions regarding economic and socioeconomic costs, including how different health care entities will be impacted, how health insurance premiums may be affected, and how access to other preventive services may be altered. We acknowledge that making preventive products available OTC without a prescription and without cost sharing has the potential to shift the economic and socioeconomic landscape in health care – especially if the scope of products includes all preventive items and services. Coding and billing processes will likely need to be updated across various systems to reflect policy changes.

12 https://www.japha.org/article/S1544-3191(22)00233-3/fulltext
While it is too early to estimate changes to premiums, we must strongly reiterate that the Tri-Departments should choose policies that help keep these products affordable and the scope of required coverage reasonable. The Tri-Departments should consider a phased approach to expanding access to OTC products and services without cost sharing and without a prescription, which can help all stakeholders evaluate economic impacts and other shifts in the market.

Many contraceptive products available to health plan members without cost sharing are sold at low prices as a result of successful market negotiations, which help keep premiums down. Any coverage of OTC contraception must maintain plans’ ability to negotiate prices with both manufacturers and retail locations, reducing total plan costs and inhibiting premium growth. From an economic perspective, plans must be able to negotiate with drug manufacturers to promote the affordability of OTC preventive products and to maintain affordability for all beneficiaries especially when they seek care in-network. This is why the ability for health insurance providers to negotiate directly with manufacturers on products that have competition are critical elements to promote affordability, furthered through health insurance provider flexibility to apply medical management tools.

Health insurance providers recognize the importance of preventive products and services to helping people get and stay healthy. We know that access to contraception, for example, can have a critical impact on consumer’s health by lowering pregnancy risk and providing symptom relief for many. However, it is unknown how much the availability of OTC contraception will impact people’s other decisions around care and possibly lower use of other preventive services. By not seeing a provider, and instead opting for an OTC product, there is the possibility that patients may miss out on opportunities to receive several critical preventive services, from behavioral health screening to cervical cancer screening. This may apply to other preventive products like tobacco cessation options as well – will that person see a provider to be screened for high blood pressure or heart disease if they opt for an OTC product that does not require a prescription for coverage? There could also be contraindications that a provider needs to communicate to a patient, and situations where a patient with certain risk factors needs to be monitored to avoid thrombotic complications, for example.

Additionally, there are important cost considerations for OTC products compared to alternatives available with a prescription. Affordability and cost effectiveness varies among different classes of OTC versus prescription products for both members and payers. When a class of drug is available both OTC and prescription, it is important that any future requirements provide necessary tools to balance affordability and access.

For any changes, we encourage the Tri-Departments to grant health insurance providers ample lead time to make adjustments for new requirements. Insurance providers will also need time to communicate changes to members, providers, and pharmacies. Additional patient education may be needed to account for changes in access to other preventive services.
Recommendations:

- The Tri-Departments should not make changes that undermine the ability of health insurance providers to negotiate prices of medications, including preventive products when available OTC, particularly to promote affordability when patients access care in-network.
- The Tri-Departments should provide health insurance providers with ample lead time to implement any new requirements on coverage of OTC preventive products available without cost sharing or prescription.