December 4, 2023

SUBMITTED VIA EMAIL: www.regulations.gov
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
Attn: 1210-ZA31

RE: Request for Information – Coverage of Over-the-Counter Preventive Services

Dear Sir or Madam:

We appreciate the opportunity to comment on the Request for Information – Coverage of Over-the-Counter Preventative Services ("the RFI") issued by the U.S. departments of Health and Human Services, Labor, and Treasury.

As background, Navitus Health Solutions is a Midwest based fully transparent pharmacy benefit manager. Since the founding of our company in 2003, Navitus has relentlessly worked to reduce the overall drug costs paid by our clients, while improving member health, providing superior customer service, and ensuring regulatory compliance. We administer pharmacy benefits for nearly eleven million members across our commercial, ACA/Exchange, Medicaid, Medicare Part D, and discount card lines of business.

While we appreciate and understand the Departments’ goal of creating a space to increase access to preventative care, we are concerned that many of our employer clients face various challenges related to administrative costs. We remain very sensitive to not creating a burden on the member for reimbursement behind implementing the expansion of preventative care, contraceptive care inclusive. Our comments will largely focus on the potential benefits and costs of offering non-grandfathered group or individual health insurance coverage to cover preventive items and services without a prescription by a provider or without cost-sharing and its impact to our client employers.

Reasonable Medical Management

Currently, the Departments’ regulations allow plans and issuers to impose reasonable medical management techniques to determine the frequency, method, treatment, or setting for coverage of a recommended preventative healthcare item or service. Custom industry standards dictate that medical management is different from that of pharmacy management. We would like to address the concerns surrounding drugs administered under a pharmacy benefit management. In the normal course of business, any tools used for pharmacy management require a prescription where the prescriber imposes controls through the prescription. If a pharmacy does not have said prescription, there is uncertainty on how to control the prescribing process and what the appropriate guardrails should be in administering a drug.

We would like the Departments’ to consider a way to mitigate this concern by requiring a prescription – whether issued by a physician or a pharmacist – to be used for the removal of any limitations for utilization management controls. The requirement to cover preventive products without cost sharing or a prescription by a health care provider would increase utilization and operational costs. However, this cost increase could be fully offset by reducing the number of physician exams that are solely conducted for the reason of obtaining a prescription. Additionally, the need to add National Drug Codes (NDC) to a formulary for coverage significantly increases complexity. PBMs would have to work with pharmacies to contract for these preventive drugs and set up an internal process for members to receive
them at the point of sale without a prescription, which is a difficult process to implement if the pharmacist does not have prescribing abilities. Since pharmacies would need to know how to establish proper claim adjudication processes, the solution for these methods may be better suited by giving pharmacies the flexibility needed to operationalize this process by having prescribing abilities and creating a fundamental systematic link between the pharmacy and health plan to determine eligibility. Without having this methodology in place, it will be impossible for the pharmacy to know the members’ eligibility.

People worldwide live with complex and chronic health care conditions, requiring support from multiple healthcare services to manage treatment. Care management and quality are of the utmost importance as it gives insight to health plans and healthcare providers on how and what patients are doing to manage their care. It would help prevent a decrease in individuals seeking normal preventive services, self-medicating, etc. Access to preventive over the counter medications should not be a replacement of medical care, but an enhancement.

**Implementation**

Because health plans do not typically have methodologies in place to reimburse expenses for OTC preventative products without prescriptions, there are not systems in place to streamline this process. We find that it is necessary for plans and issuers to be able to have the essentials necessary to apply reasonable techniques to avoid the potential for fraud, waste, and abuse, as well as any increase in health care costs for participants and plans.

We would like the Departments to consider giving employers and plans the flexibility and time needed to develop their own systems in order to implement various options to overcome the challenges of purchasing OTC preventive products at the pharmacy counter with no reimbursement or cost sharing. Simultaneously, we recommend that the Departments’ provide clear guidelines on the implementation of these system requirements.

Thank you for the opportunity to provide feedback on this request for information. If we can provide any additional information for your rule-making process, please let us know.

Respectfully,

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