

Exploring Implications of the Nonprescription Drug Safe Use Regulatory Expansion (NSURE) Initiative on Reimbursement and Access**Background**

Pharmaceutical care plays a critical role in supporting the health of patients and consumers in the United States (U.S.). However, many in the U.S. lack regular access to medications, an issue which contributes to the medical undertreatment of many common diseases and conditions.^{1,2,3} Low rates of medical adherence and a failure to administer recommended therapy may also contribute to this problem, as research suggests 20% to 30% of prescription medications are never filled and 50% of medications for chronic disease are not taken as prescribed.⁴ Improving access to appropriate pharmaceutical care while ensuring that drugs are used safely and effectively can help to mitigate the problem of undertreatment. Overcoming medical undertreatment will require action by all health care stakeholders, including providers, patients, payers, regulators, and medical product manufacturers.

In an effort to address the impact of undertreatment on public health, the U.S. Food and Drug Administration (FDA) is exploring how a regulatory expansion of the nonprescription drug class might increase access to medications for undertreated diseases and conditions. Through the *Nonprescription Drug Safe Use Regulatory Expansion (NSURE)* initiative, FDA is exploring one potential strategy for mitigating the problem of undertreatment through FDA's existing authorities. The NSURE initiative is aimed at identifying how Conditions of Safe Use might be developed and implemented as part of a comprehensive approach to drug regulation that ensures that certain drugs will be safe and effective in the nonprescription setting.

The NSURE initiative has the potential to increase access to important medications and can serve as a new mechanism to bring undertreated patients into the healthcare system. An essential component of this initiative is to explore how health care professionals or innovative technologies can serve as a condition to the safe use of drugs in a nonprescription setting. Through a cooperative agreement with FDA, the Engelberg Center for Health Care Reform at the Brookings Institution convened two expert workshops which explored these issues.

The first expert workshop, held on November 8, 2012, explored issues and practical considerations in the development of Conditions of Safe Use which utilize health care professionals. Stakeholders investigated strategies and opportunities for health care professional to utilize their existing practice

¹ Shrank W, et al. The Quality of Pharmacologic Care for Adults in the United States. *Medical Care* 44(10): 936-56

² Kenney G, et al. A Decade of Health Care Access Declines for Adults Holds Implications for Changes in the Affordable Care Act. *Health Affairs* 2012; 31: 5899-908

³ McGlynn E, et al. The Quality of Health Care Delivered to Adults in the United States. *New England Journal of Medicine* 348(26): 2635-645

⁴ Viswanathan M, et al. Interventions to Improve Adherence to Self-administered Medications for Chronic Diseases in the United States: A Systematic Review. *Annals of Internal Medicine*. 2012 Dec; 157(11):785-795.

and discussed lessons from previous initiatives which expanded access to pharmaceuticals. A summary of the workshop discussion is available on the Brookings event [webpage](#).

The second expert workshop, held on May 9, 2013, investigated the use of technologies as a Condition of Safe Use for medications within a nonprescription setting. This workshop explored stakeholder perspectives on the role of technology to support the safe and effective use of nonprescription products and investigated the integration of innovative technologies, such as mobile applications and in-store kiosks, into the existing health care delivery system. A summary of the workshop discussion is also available on the Brookings event [webpage](#).

Meeting Objectives and Scope

While the NSURE initiative has the potential to expand the availability of nonprescription medications, it will be critical to understand the initiative's impact on patient access and reimbursement. In an effort to further investigate these issues, the Engelberg Center for Health Care Reform at Brookings convened the third expert workshop, "Exploring Implications of the Nonprescription Drug Safe Use Regulatory Expansion (NSURE) Initiative on Reimbursement and Access." At this expert workshop, a wide range of experts explored previous effects from prescription-to-nonprescription medication switches, identified potential incentives for coverage of nonprescription drugs with Conditions of Safe Use, and investigated potential strategies for reimbursement. This document highlights the major points of discussion.

Effect of Previous Prescription-to-Nonprescription Switches

Participants discussed the effect of previous prescription-to-nonprescription (Rx-to-OTC) switches on cost, utilization, and public health. A summary the discussion is highlighted below.

Context of Rx-to-OTC Switches

In the U.S., Rx-to-OTC switches have enabled a range of medications to become widely available in the pharmacy and retail settings. Most recently, therapies approved to treat allergies, acid-reflux, and over-active bladder have been made available as nonprescription.⁵ Participants noted that while novel therapeutic areas have been introduced in recent years, the total number of switches within this decade has decreased compared to historical levels.⁶

Participants noted that many Rx-to-OTC products maintain both a prescription and nonprescription status, though the two products can vary slightly in their dosage, strength, or form.⁷ While the NSURE initiative is distinct from Rx-to-OTC switches, lessons can be learned from its successes and failures regarding reimbursement and access.

Effect on Cost

The cost implications of an Rx-to-OTC switch depend on a great number of factors, including the availability of nonprescription competitors, the novelty of the switch, product exclusivity, and other class effects. However, the cost of medications has generally decreased in price following a switch from

⁵ U.S. Food and Drug Administration (October 2013). Prescription to Over-the-Counter (OTC) Switch List (page). Retrieved December 23, 2013 from, <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm106378.htm>

⁶ Soller R W, et al. OTC Considerations for Rx-to-OTC Switch. *SelfCare* 2011; 2(5):117-138

⁷ Harrington P, et al. Analysis of the Movement of Prescription Drugs to Over-the-Counter Status. *Journal of Managed Care Pharmacy* 2002; 8(6) 499-508

prescription to nonprescription status. Participants noted that this trend is especially true for generic medications in the nonprescription setting.

For patients and consumers, the savings from lower cost nonprescription medications is often offset by a loss of coverage and reimbursement in the nonprescription setting. This results from third-party payers dropping coverage following an Rx-to-OTC switch. As coverage varies among health plans, the impact of an Rx-to-OTC switch on an individual level can be highly variable and drug-specific. Participants noted that patients often weigh the costs of copayments, out-of-pocket expenses, and individual preferences in making their purchasing decisions.

While cost savings of Rx-to-OTC switches can be substantial, most of the savings comes about through a cost-shift from payers to consumers and patients. Participants estimated that approximately 85% of cost savings are for third-party payers. Many of the most significant cost savings result from a decrease in expenditures from medical encounters and physician visits for the sole purpose of obtaining a prescription. Additionally, research has shown a decrease in emergency room visits as a result of increased access to early treatment for acute symptoms. This has the potential to result in savings for both payers and patients.

Participants discussed a number of former Rx-to-OTC switches and their effect on cost, including:

- Allergy medications: Following a 2002 switch of loratadine, the nonprescription medication was generally found to be a lower-cost alternative for both insured and uninsured consumers.
- Heartburn medications: The Rx-to-OTC switch of omeprazole resulted in cost savings for many patients who had previously received prescription coverage.

Effect on Access and Utilization

In general, Rx-to-OTC switches provide increased access to medication and enhanced rates of utilization. Participants noted that the Rx-to-OTC switch of nicotine replacement therapies (e.g., nicotine patches) provided important insights into the effect of a switch on access and utilization. Following the increased availability of nicotine replacement therapies, patient utilization increased approximately 150% from previous prescription rates.⁸ Participants noted that this increase in utilization corresponded with FDA requirements for age verification, surveillance, and additional smoking cessation programs. Participants noted that doctors remained an important component of these programs, and that many physicians remained involved in smoking cessation therapy following the Rx-to-OTC switch.

Participants also discussed the Rx-to-OTC conversion of drugs such as antihistamines, emergency contraceptives, proton-pump inhibitors, and weight loss medications. Significant increases in drug utilization were found for most of the drugs discussed. It was estimated that the introduction of a nonprescription medication following an Rx-to-OTC switch resulted in an average 30% increase in utilization.⁹ Participants also discussed the potential increases in utilization for the additional Rx-to-OTC switches of therapies for cholesterol, erectile dysfunction, incontinence, migraine, and sleep aids.¹⁰

⁸ Burton S L, et. al. Use of FDA-approved pharmacologic treatments for tobacco dependence--United States, 1984-1998. *MMWR Morb Mortal Wkly Rep.* 2000 Jul 28; 49 (29):665-8.

⁹ Stomberg C, et al. Utilization effects of Rx-OTC switches and implications for future switches. *Health* (5) 2013; 1667-1680.

¹⁰ Ibid.

Effect on Public Health and Health Outcomes

Participants remarked that in general, medication utilization increases following an Rx-to-OTC switch, and that this increase provides opportunities for improved health outcomes. In particular, participants discussed the public health benefit of nonprescription availability of nicotine replacement therapies. Following the Rx-to-OTC switch, an estimated 200,000 additional persons were able to quit smoking, thereby providing patients with an increased average life expectancy as well as providing large societal public health benefits.¹¹

While Rx-to-OTC switches have demonstrated a public health benefit following a switch, participants noted that further research is needed to evaluate the precise effects in low-income populations. It was noted that many people within this population have difficulty affording medications regardless of prescription or nonprescription status, and that this population is particularly susceptible to price sensitivity. To date, the public health benefits of Rx-to-OTC switches are not well understood in this population.

Value and Incentives for Payers to Provide Coverage for NSURE Medications

Participants discussed potential incentives for payers, Accountable Care Organizations (ACOs), managed care organizations, and other stakeholders to provide coverage for nonprescription medications with Conditions of Safe Use. A summary of that discussion is highlighted below.

Background Considerations

Participants raised a number of important factors and considerations that could influence payer coverage decisions for NSURE medications. Participants noted that while payers do not generally provide coverage and reimbursement for nonprescription drugs, a select number of nonprescription products are eligible for coverage through public and private programs. These programs often provide nonprescription assistance through Medicaid, Veterans Affairs, Tricare, Indian Health Service, as well as private payers, though many programs require a written prescription from a provider for coverage. Recent reforms have also mandated physician authorization for reimbursement of nonprescription medications through tax-exempt savings accounts such as Flexible Spending Accounts, Health Reimbursement Arrangements, and Health Savings Accounts.

Incentives for Nonprescription Coverage

Participants noted multiple considerations that factor into payers' decision-making for coverage and reimbursement. Beyond the cost of the medication, an important payer consideration is the potential for improved health outcomes of its membership, given the potential to reduce total healthcare costs. Therefore, if a product has demonstrated an impact on improving cost of care or increased quality of care, payers may be incentivized to extend coverage in the nonprescription setting to improve patient health outcomes and/or decrease overall healthcare delivery costs over time.

A number of short-term cost reductions may arise for payers who choose to provide coverage and reimbursement for nonprescription medications with Conditions of Safe Use. If the switched product is a low cost alternative to the prescription version, payers may have immediate reductions in cost. Participants remarked that increased medication adherence to nonprescription medications with Conditions of Safe Use may also provide payers a strong incentive for coverage. Employee health plans may be willing to provide coverage for medications if increased utilization of the product can lead to

¹¹ Shiffman S. "Nicotine Replacement Therapy: Case Study of OTC Switch Benefits." Brookings Institution. Washington, D.C. November 4, 2013. Presentation.

greater work productivity or lower overall costs. Additionally, payers may see a competitive advantage in offering additional nonprescription benefits that have not been traditionally covered by health plans. This has the potential to serve as a selling point to attract additional clients.

The long-term incentives for payers to cover medications will vary depending on the nature of the condition and type of the cost offset. For acute conditions such as migraines, it may be unlikely that payers will provide coverage, unless there is a clear and direct cost reduction, such as in the case of cheaper generic nonprescription medications within the class. For conditions such as asthma and allergic reactions, nonprescription access might allow patients to avert more significant adverse outcomes and costlier emergency room visits, resulting in significant cost savings. For more chronic conditions, payer incentives may vary depending on the time frame of the cost offset and the type of value that the medication brings to patients. Participants noted that health plans typically consider a 3-5 year timeframe for costs to offset from an outcomes perspective. This timeframe will factor into payer motivation and incentive for providing coverage for therapies that treat chronic conditions.

Participants also noted the worsening shortage of primary care physicians, emphasizing that physicians' time should be maximized to focus on the most complex cases. Avoidable interactions with health care providers can come at a steep cost, including the opportunity cost for physicians and health care providers' time being occupied by such visits. The NSURE initiative may help to reduce physician visits and medical encounters that are conducted for the sole purpose of obtaining a prescription. This potential reduction demonstrates an additional opportunity for payer cost savings.

Tracking Nonprescriptions in Claims Data

If payers extend coverage to nonprescription medications with Conditions of Safe Use, they will be able to track the purchase and use of these medications through claims transaction processes. Tracking use of these medications will be beneficial to payers, as this information can help with quality reporting, utilization analysis, identification of gaps in care, and the tracking of safety, cost, and health outcomes. This will provide additional insights into the value of Rx-to-OTC switched medications, as nonprescription medications are not currently tracked within the claims transaction process. Furthermore, as the claims adjudication process is initiated by pharmacy dispensing systems, pharmacists will be better able to monitor for potential drug-drug interactions for covered nonprescription medications.

Challenges and Strategies in Coverage and Reimbursement of NSURE Medications

Participants discussed a number of challenges, as well as potential solutions, in the coverage and reimbursement for NSURE medications. A summary of those topics are highlighted below.

Processing Nonprescription Claims

The claims processing and adjudication process plays a central role in providing coverage for medications. Generally, pharmacy dispensing systems and claims adjudication systems require the identification of a prescriber via a National Provider Identifier (NPI) in order for a claim to be processed and paid. This has typically led to the requirement of a written prescription by a provider in order for a nonprescription medication to be covered by payers. Without the ability to adjudicate the claim for nonprescription medications, issues may arise in providing patient coverage at the point-of-purchase. Given the technical challenges associated with claims adjudication of nonprescription medications, participants discussed a number of potential solutions. Participants noted that nonprescription medication coverage should be conducted through normal claims systems to help ensure safety and the appropriateness of care.

One option is to require patients to receive a written prescription from a provider in order to receive nonprescription coverage. This would likely require patients to see a physician in order to obtain the prescription. For patients and consumers who have insurance and access to primary care physicians, this option may still optimize utilization. However, this option may negatively impact the initiative's intended effort of reducing barriers for underserved and untreated populations. This requirement would impose an additional requirement for those populations, as consumers will require access to a health care professional with prescribing authority for coverage and must pay the costs associated with the encounter (e.g., copayment).

A second option is to overcome the prescription requirement through technical fixes within pharmacy and payer settings. For example, pharmacists may be able to submit the pharmacy claim by using proxy codes in place of an NPI number. In Florida, pharmacists have already implemented a Medicaid nonprescription drug benefits program which is able to adjudicate the claim without the use of a prescription or NPI. A number of pharmacy benefit management companies have worked with pharmacy chains to implement this system and instruct pharmacists on proper procedures. Participants remarked that while the program has been successful, there may be difficulties in expanding this into a nationally uniform system. In particular, regulatory changes will likely be required on a state-by-state basis with approval from each individual state board of pharmacy.

Identifying and Designating NSURE Medications

Given the number of nonprescription drugs which are approved for marketing each year, participants noted that in general, payers will be reluctant to evaluate every nonprescription medication as a candidate for reimbursement. Some participants noted that without a clear indication as to which medications fall under the NSURE initiative, plan sponsors will have difficulty determining which nonprescription medications are intended to address medical undertreatment through increased access. As such, plan sponsors may be less willing to offer coverage or reimbursement following an RX-to-OTC switch.

Participants noted that third-party payers might benefit from a designation that distinguishes NSURE nonprescription medications from other nonprescription medications, as these products might be candidates for coverage. This designation can facilitate the selection and coverage of high-value nonprescription medications. Participants noted that the NSURE product designation could be developed through industry collaboration or an FDA classification. While this designation would not represent a new class of drugs, it would encourage regulators and payers to specify a subgroup of nonprescription medications as valuable candidates for coverage and reimbursement. It was also noted that pharmacists would benefit from knowing which medications fall under the NSURE initiative. Pharmacists could use this information when counseling patients who may be candidates for an NSURE product, as well as patients who may not need a prescription for their current medications going forward.

Incentiving NSURE Medications through Copayment Tiers and Deductibles

The formulary decision-making process will be a key component in determining coverage and reimbursement. If NSURE medications demonstrate the potential to improve health outcomes, payers can work to structure tiered coverage, copayments, and formularies to incentivize their usage. Participants discussed a case study in which a self-insured employer group incentivized the purchase and dispensing of Rx-to-OTC heartburn medications. Through the use of copayments, large dispensing quantities, and pharmacists' compensation, the health plan was able to incentivize the purchase of

nonprescription medications. These actions ultimately resulted in cost saving for patients and payers, and provided a small increase in utilization. Participants noted that the use of such incentives can encourage the uptake and utilization of NSURE medications.

Utilizing Dual-Status Medications

Medications that maintain dual-status (i.e., a drug that may be obtained either as prescription or nonprescription) provide additional options for patients to access and purchase products. Through dual-status, patients can weigh their decision based on co-payments, out-of-pocket expenses, and personal preferences. In particular, this will ensure that underserved populations will have the option to purchase medication through prescription coverage or nonprescription availability.

Additional Considerations

Participants discussed a number of additional considerations for the NSURE initiative moving forward. A summary of those topics are highlighted below.

Potential for Abuse

With coverage of nonprescription medications, payers must be mindful of the potential for abuse and hoarding of medications. Providing a maximum cap of coverage for each medication could help payers to ensure that patients and consumers are not inappropriately purchasing or utilizing NSURE medications. Participants recommended that payers actively manage the use of such medications to ensure that the quantities offered are safe and appropriate.

Safety Issues

Highlighting previous expert-workshop discussions, participants noted the need for appropriate safeguards to ensure the safe and effective use of medication. Conditions of Safe Use can help to facilitate self-care by addressing barriers at critical points in the self-diagnosis of condition, self-selection of medication, and self-management of therapy. Participants recommended that stakeholders continue to explore how Conditions of Safe Use can be safely and effectively integrated within the existing healthcare system.

Barriers at the Point-of-Purchase

Additional barriers at the point-of-purchase have the potential to reduce utilization of nonprescription medications. Participants discussed previous examples of U.S. retail outlets that chose to place nonprescription nicotine replacement therapies behind the pharmacy counter, requiring a pharmacist or clerk assistance for purchase. These retail outlets observed an average 30% reduction in the sale of the product, as compared to retail settings which offered the smoking cessation product off-the-shelf.¹² This reduction in utilization has been attributed to privacy concerns, limited pharmacist and clerk availability, longer wait times, and limitations in rural access. This example illustrates the potential for barriers at the point-of-purchase to have a large effect on patient decision-making. Participants also discussed the utilization of statins in the United Kingdom, where pharmacists are permitted to dispense low-dose statins after performing pharmacy-based supervision and consultation services. This barrier also negatively influenced consumers' willingness to utilize the medication. Moving forward, participants noted that consumer behavior and patient decision-making will provide important insights into the development of the NSURE initiative.

¹² Shiffman S. "Nicotine Replacement Therapy: Case Study of OTC Switch Benefits." Brookings Institution. Washington, D.C. November 4, 2013. Presentation. Survey results provided by major U.S. national retailer, GSK NRT sales, 52 wks. ending July 31, 2007.

Additional Cost Issues

Participants discussed the potential for increased healthcare costs stemming from ancillary service from Conditions of Safe Use. Additional costs may result from services such as pharmacist counseling or in-store diagnostic technologies, though these services may also have the potential for coverage and reimbursement. Participants noted that health care professionals may also face increased professional liability from performing these services.

Conclusion

This expert workshop explored the potential effect of the NSURE initiative on reimbursement and access, as well as investigated the value of coverage and reimbursement for nonprescription medications with Conditions of Safe Use. FDA and stakeholders will continue to explore the use of health care providers, technologies, and medication coverage to inform the development of the NSURE initiative.