

# Perspectives on Nonmedical Switching and the COVID-19 Pandemic: A Narrative Review

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**N**onmedical switching (NMS) is a change in a patient's treatment regimen for reasons other than lack of efficacy, intolerance, adverse effects, or poor patient adherence.<sup>1</sup>

NMS may result from an agreement between pharmacy benefit managers or health plans and a biologic manufacturer, resulting in formulary changes that include a specific manufacturer's product as a preferred treatment. These formulary changes may be used by insurers as a cost-saving strategy in response to rising health care costs.<sup>1</sup> As a result, insurance may no longer cover a patient's prescribed medication or may cover it at a higher patient out-of-pocket cost, often with the requirement that patients first try the preferred product. In some instances, insurers may offer patients a direct financial incentive for switching to a preferred therapy.<sup>2</sup> If patients wish to continue their current medication, lack of coverage or higher patient costs can make it prohibitively expensive.<sup>3</sup>

NMS is employed by payers on the premise that therapeutic substitutes (eg, biosimilars, in-class alternatives) have efficacy and safety comparable with the reference therapeutic. This premise is appropriate only when well-designed head-to-head bioequivalence studies support comparable efficacy and safety. Even when clinical studies support comparability, real-world evidence has shown that NMS to in-class alternatives (eg, switching between tumor necrosis factor inhibitors) can decrease effectiveness and increase adverse effects.<sup>4</sup> Limited data are available to help guide clinical decision-making regarding use of washout periods, loading doses following a switch, or comparative safety of switching to a biosimilar, an in-class alternative, or a drug with a different mechanism of action.<sup>5-7</sup>

Prescription drug spending is among the fastest growing health care spending categories, with growth attributable to higher prices and the availability of new drugs.<sup>8</sup> Rising health care costs are a substantial burden on society, and even patients with insurance may not be able to afford biologic therapies because of high co-pays and out-of-pocket costs. In light of the rising costs of prescription medications, biosimilars and in-class alternatives may appear to be the most cost-effective option for insurers. Lower overall costs for insurers and health plans could potentially lead to wider patient access to therapies; however, transparency around the pricing and

## ABSTRACT

**OBJECTIVES:** Nonmedical switching (NMS) is a change in a patient's treatment regimen for reasons other than lack of efficacy, intolerance, adverse effects, or poor adherence. We describe the impact of NMS on patients, health care workers, and health systems, focusing on NMS to in-class biologic alternatives in US patients with chronic, immune-mediated rheumatic and dermatologic conditions. Additionally, we evaluate the ways in which the COVID-19 pandemic may exacerbate the physical, psychological, and economic impacts of NMS.

**STUDY DESIGN:** Narrative review.

**METHODS:** We performed a search of MEDLINE's PubMed database from October 2015 to October 2020, with a repeat search in October 2021. Search terms included relevant keywords pertaining to NMS, biologics, and disease areas. Results were supplemented by a search of key congress abstracts from 2015 to 2021 and a targeted internet search.

**RESULTS:** NMS increases medication abandonment, errors, and adverse effects, and it can lead to longer patient visits, increased follow-up visits, additional laboratory tests and procedures, and greater overall health care resource utilization (HCRU). The increased HCRU associated with NMS increases patients' financial burden due to additional co-pays and out-of-pocket costs.

**CONCLUSIONS:** The decision to switch treatments should result from shared decision-making between health care providers (HCPs) and patients to achieve the best clinical outcomes and optimal HCRU. The issues related to NMS may be compounded by the financial and psychosocial stress on HCPs and patients created by the COVID-19 pandemic. HCPs should advocate for continuous patient treatment and be familiar with continuity of care legislation, appeals processes, and manufacturer assistance programs.

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**TAKEAWAY POINTS**

This review describes the impact of nonmedical switching of biologic therapies on US patients and providers, with a focus on switching to in-class alternatives.

- ▶ Nonmedical switching can negatively affect patient outcomes and increase health care provider administrative burden and health care resource utilization and costs; this is important because health care workers and patients may experience psychosocial, administrative, and financial stressors due to the COVID-19 pandemic.
- ▶ Survey studies and society position statements indicate that most patients and providers believe that treatment changes should be based on shared decision-making and not be driven by formulary changes or insurers as a cost-saving measure.
- ▶ Provider familiarity with continuity of care legislation, appeals processes, and manufacturer assistance programs can ensure that patients continue to receive needed therapy.

publications (Figure 1). Search terms included relevant keywords pertaining to NMS (eg, non-medical switching AND [cost OR {biologics OR biosimilars} OR patient outcome OR {quality OR care}]; nocebo AND [biologic OR biosimilar] AND [immunology OR inflammatory]; autonomy AND [prescriber OR prescribing] AND biologic; [physician OR patient] AND non-medical switching AND [perspective OR attitude OR opinion OR preferences]; and non-medical switching AND burden AND [office management OR staffing OR administrative]), with a focus on NMS of biologics to in-class alternatives

rebates for preferred therapies that lead to formulary changes and NMS is needed.<sup>9</sup>

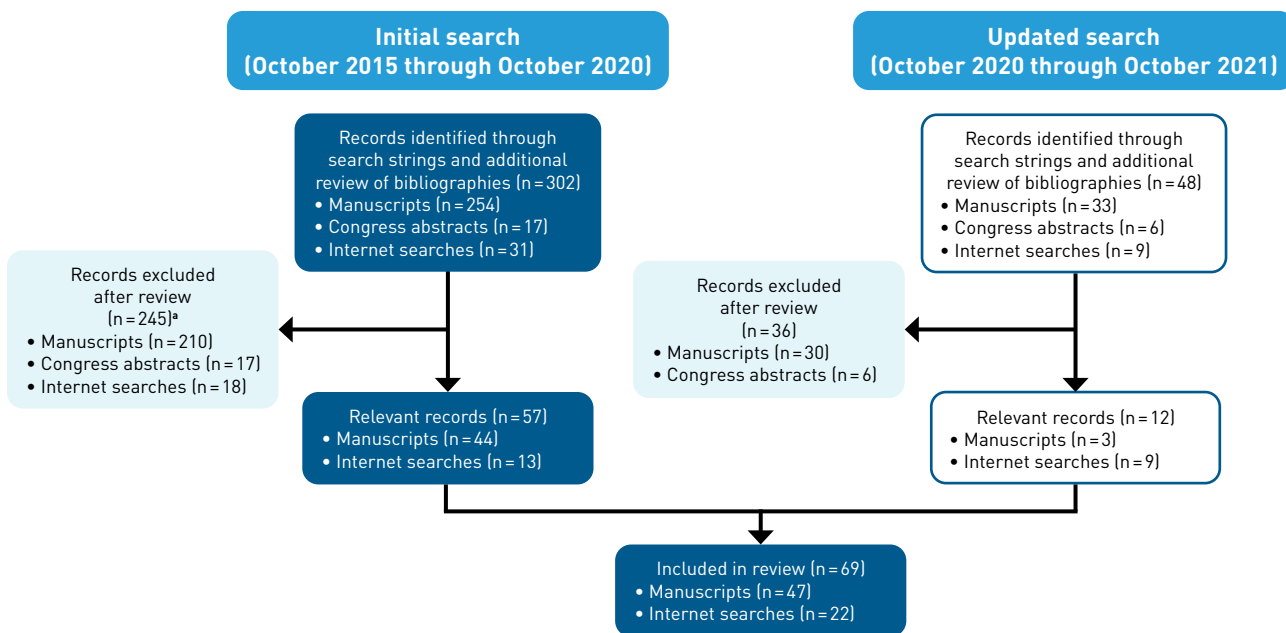
The purpose of this narrative review is to describe the impact of NMS on patients, health care workers, and health systems, with a focus on NMS to in-class biologic alternatives in US patients with chronic, immune-mediated rheumatic and dermatologic diseases. In addition, we evaluate the ways in which the COVID-19 pandemic may exacerbate the negative physical, psychological, and economic impacts of NMS.

**Statement of Literature Search**

We performed a search of MEDLINE's PubMed database from October 2015 to October 2020, with a repeat search in October 2021 for any new

in US patients with rheumatic and dermatologic diseases. These search terms were identified by a preliminary review of key terms in relevant publications. Additional manual searches, including references pulled from bibliographies of articles in final search results, were also performed. We supplemented results from PubMed by searching for relevant keywords (eg, non-medical switching OR switching OR substitution OR treatment patterns OR reasons) in abstracts published within the past 6 years from large US rheumatology, dermatology, managed care pharmacy, and health economics and outcomes research congresses, as well as a targeted internet search (eg, key societies, organizations, US news sites). The authors reviewed the manuscripts, abstract presentations, and findings from the targeted internet search, and the hits that

**FIGURE 1.** Overview of Search Strategy<sup>a</sup>



<sup>a</sup>Some records from internet searches (eg, society statements) were excluded from the initial search window because they were updated after October 2020; some congress abstracts were excluded because they were subsequently published as full-length manuscripts and included in the review.

most comprehensively captured the objectives were ultimately included in this review. This strategy identified studies assessing health care provider (HCP) and patient perspectives regarding NMS in US clinical settings; however, HCP and patient viewpoints were not directly queried by the authors beyond those studies identified in the literature search.

## Perspectives on NMS

**Physician/HCP perspectives and impact on clinical practice.** HCPs often anticipate negative effects of NMS on patient outcomes, health care resource utilization (HCRU), and clinical practice (Figure 2<sup>10-13</sup>). Physicians have reported that NMS increased medication abandonment, medication errors, and adverse effects.<sup>11</sup> Additionally, more than 50% of physicians anticipated negative impacts of NMS on office management, treatment efficacy, patient mental health, and safety.<sup>10</sup> Many HCPs also believe that NMS undermines their autonomy and clinical judgment, forces them to take responsibility for treatment decisions made by insurers, compromises their ethics, and results in treatment that is inconsistent with clinical guidelines.

In a survey of 320 US rheumatologists, 73% indicated they would be comfortable initiating treatment with a biosimilar in a biologic-naïve patient, but only 35% would switch a patient doing well on a reference biologic.<sup>14</sup> In a survey of more than 1000 practicing physicians, 73% were infrequently amenable or not amenable to insurance-mandated NMS, the primary factor being patients' stability on their current medication.<sup>13</sup>

HCPs, medical societies, and patient advocacy groups acknowledge the potential negative impacts of NMS on patients and the importance of HCP autonomy and shared decision-making. Many medical societies have commented on or established formal positions regarding NMS and oppose NMS for patients on stable therapy (Figure 3<sup>15-19</sup>).

**Patient perspectives and impact on patient outcomes.** In US surveys, patients opposed NMS, stating concerns regarding potential loss of disease control, increased adverse effects, not knowing enough about the medication, and lack of sufficient information to support switching (Figure 4<sup>20-25</sup>). In surveys by the Global Healthy Living Foundation and CreakyJoints, more than 50% of respondents tried multiple medications before finding one that worked and felt that after NMS, their new medication was less effective.<sup>22-25</sup> Respondents frequently reported visiting their HCP or the emergency department (ED) for new adverse effects and missing work or having less time with family and friends due to adverse effects or loss of disease control after NMS. Approximately half reported a treatment delay for administrative reasons, such as pending insurance authorization. Treatment delays for administrative reasons can interfere with maintenance of disease control and lead to adverse effects, and similar results were observed in a survey of patients undergoing NMS from a reference biologic to a biosimilar.<sup>21</sup>

Studies suggest that the impact of NMS on patient outcomes is affected by patient-related factors and subjective, nonspecific effects.<sup>26-28</sup> Numerous studies have shown a "nocebo" effect (ie,

negative expectations leading to a negative treatment response) in patients switching to a biosimilar, resulting in worse clinical and patient-reported outcomes, decreased treatment satisfaction, and increased HCRU.<sup>28-30</sup> The nocebo effect occurs whether or not the patient has a choice to switch but occurs more frequently when they do not.<sup>28,30</sup> Although research has shown that effective communication between HCPs and patients can improve acceptance of biosimilars and decrease the risk of the nocebo effect,<sup>31</sup> this requires additional HCP and staff time and supports the need for shared decision-making by HCPs and patients when switching medications.

**Impact on HCRU and cost.** Physicians have reported that NMS results in longer patient visits, increased follow-up visits, additional laboratory tests and procedures, and greater overall HCRU.<sup>10-13,32</sup> Undergoing NMS to therapeutics that require loading doses increases the number of visits in the weeks following the switch, and self-administered drugs require patient training; when multiple patients undergo NMS, these factors can contribute to a substantial increase in HCP and staff time.

NMS is associated with higher rates of HCRU, including follow-up office visits and increased laboratory tests and procedures.<sup>4,11,12,32-34</sup> NMS can also increase the number or frequency of medication-related adverse consequences that further increase the need for additional HCRU, including new or more severe adverse effects that result in hospitalization.<sup>4,11,12,32</sup> As a result, NMS may lead to higher overall costs for insurers.

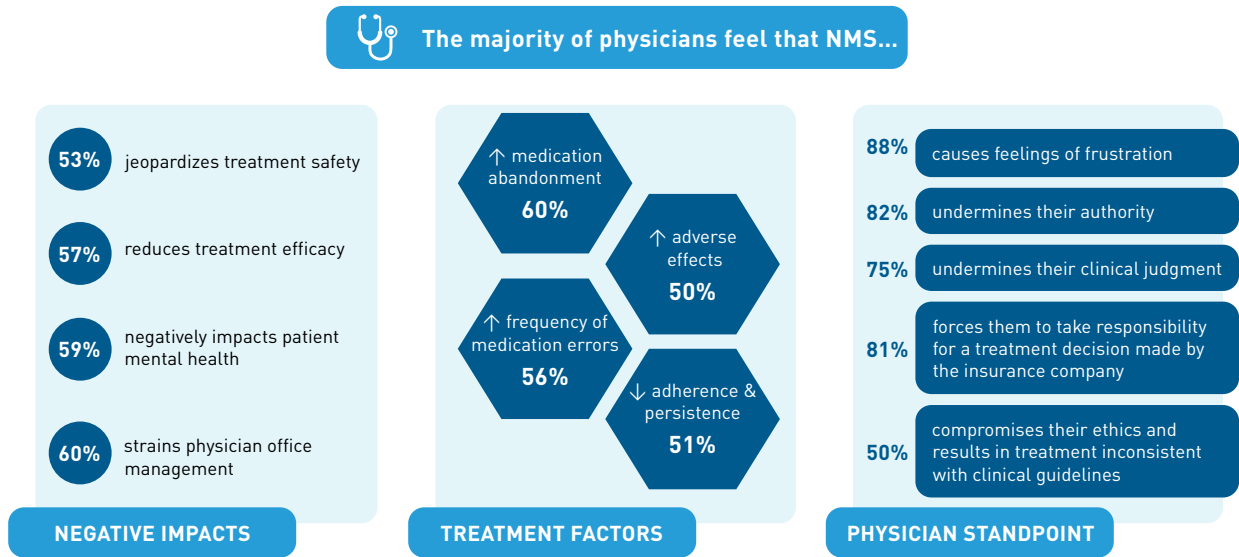
Implementation of NMS is complex and requires communication among HCPs, support staff, patients, pharmacists, pharmacy staff, and insurers. Physicians have reported that insurers do not optimally communicate about alternative medications, procedures, timelines, or methods to track challenges when NMS is required.<sup>13</sup> Submitting prior authorization forms or appeals when coverage is denied and educating patients about manufacturer assistance programs can help prevent NMS but require additional HCP and staff time, which can disrupt patient care.<sup>35,36</sup>

The increased HCRU associated with NMS also increases patients' financial burden because of additional co-pays and out-of-pocket costs for office visits, laboratory tests, and procedures. Laboratory tests, in particular, can increase patient financial burden because they are typically billed separately from office visits.<sup>11,12</sup> Patients can also incur indirect costs through missed work from disease flares or severe adverse effects associated with NMS.<sup>22-25</sup>

## Perspectives on the COVID-19 Pandemic

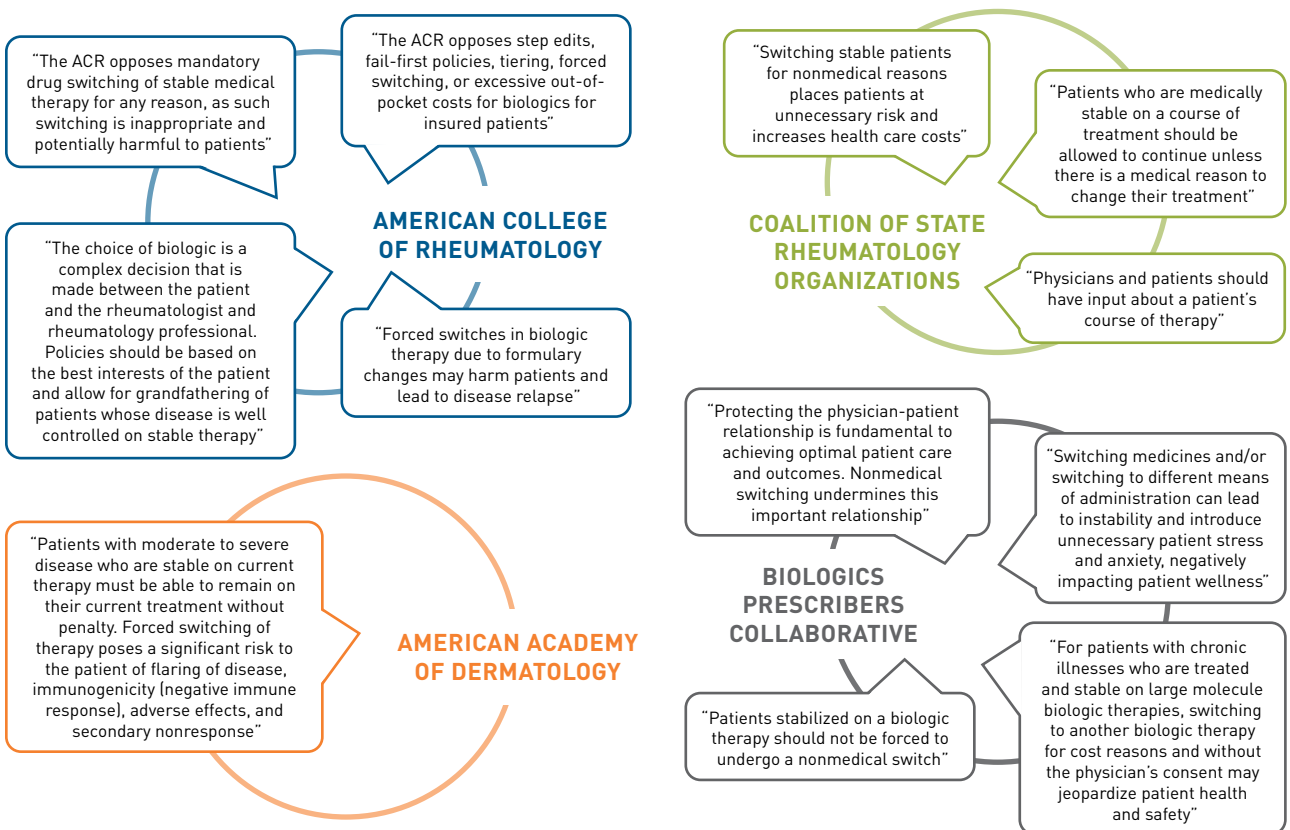
**Impact on health care.** The COVID-19 pandemic has placed additional stressors on health care workers' emotional resilience.<sup>37,38</sup> Interviews with HCPs showed increased anxiety due to potential lack of appropriate personal protective equipment or other resources, risk of infection of self or loved ones, and being underprepared to take on new roles to cover gaps in the clinical workforce in areas with many patients with COVID-19.<sup>39</sup> Health care facilities have had to adjust daily operating procedures to reduce the risk of

FIGURE 2. Physician Perspectives on NMS<sup>10-13</sup>



NMS, nonmedical switching.

FIGURE 3. Physician Organization Position Statements on NMS<sup>15-19</sup>



ACR, American College of Rheumatology; NMS, nonmedical switching.

**FIGURE 4. Patient Perspectives on NMS<sup>20-25</sup>**



**Patient apprehensions about NMS**

**PATIENT APPROACH**

**85%** did not want to switch to a biosimilar if their current biologic was helping their disease

**79%** of patients who received notification about NMS took  $\geq 1$  action to avoid NMS

**98%** disapproved of switching biologics without patient and provider consent

**Up to 94%-98%<sup>a</sup>** supported legislation preventing financial pressure from insurers to switch their physician-prescribed medication for nonmedical reasons

**Up to 89%-94%<sup>a</sup>** indicated that the out-of-pocket medication cost was at least a somewhat important factor in their decision-making process

**EXPERIENCE AFTER NMS**

**~93%** experienced worse adverse effects

felt their new medication was less effective **~72%**

**46%** saw their health care provider or visited the emergency department because of new adverse effects

had to try multiple medications before finding one that worked **61%**

**95%** reported reduction in the time spent with family/friends because of loss of disease control

reported delay in receiving medication for administrative reasons because of switching **49%**

**41%** reported missing work

marketplace enrollment and shifts in member coverage.<sup>41</sup> Although increased enrollment in Medicaid and individual marketplace plans has been lower than expected, uncertainty remains regarding the long-term impacts of COVID-19 on public and private coverage and insurance premiums, insurer cash flow due to decreased elective procedures, deferred care for conditions unrelated to COVID-19, and delayed payments. This financial uncertainty may lead to increases in cost-saving measures such as formulary changes resulting in NMS.

**Impact on patients and health outcomes.**

Patients with chronic illness experience substantial psychosocial burdens, including depression and anxiety, as a result of their disease and associated comorbidities,<sup>44</sup> and they face heightened anxiety in the pandemic setting. Patients with chronic disease have reported concerns about disruption or lack of access to medication and quality health care, loss of income or insurance, isolation from family and friends, inability to work for fear of contracting SARS-CoV-2 in the workplace, and the impact of their disease or medication on outcomes of COVID-19 should they be infected.<sup>45,46</sup> Although evidence is mixed for more severe COVID-19 complications in patients with autoimmune disease,<sup>47,48</sup> patients frequently expressed concern that their immunocompromised status, immunosuppressive therapy, and disease-related comorbidities could increase their risk of SARS-CoV-2 infection, more severe COVID-19 outcomes including death or the need for a

ventilator, and longer and more difficult recovery. Patients also worried about shortages of their medications, and some reported actively or potentially delaying treatment to avoid entering health care facilities or overburdening health care systems. These concerns may be particularly relevant for patients undergoing NMS to a medication that requires in-clinic loading doses. Patient hesitancy to visit health care settings may increase the likelihood of missed visits and therefore missed doses. Limiting NMS during a pandemic can prevent additional challenges to patients' emotional resilience.

Anxiety about risk of SARS-CoV-2 infection in health care facilities may increase the risk for negative patient health outcomes following NMS. Interviews with patients indicate that patients view hospitals and EDs as reservoirs of infection with a high risk for contracting SARS-CoV-2.<sup>49,50</sup> In a poll by the American College of Emergency Physicians, nearly three-fourths of respondents indicated they were concerned about hospital wait times, overcrowding, or overstressed health care systems, and almost one-third had delayed or avoided seeking care due to concerns about contracting SARS-CoV-2.<sup>50</sup> Despite

NMS, nonmedical switching.

<sup>a</sup>Ranges reflect findings from multiple references.

SARS-CoV-2 transmission, increasing the administrative burden in HCP offices.<sup>40</sup> Additional staff responsibilities include screening and triage of patients to determine which patients should be monitored through telehealth, treated in-office, or referred to emergency care; monitoring patients at home via calls, texts, patient portals, or other means; and instructing patients and caregivers on at-home monitoring and care, use of telehealth platforms, and safe use of health care facilities.<sup>40</sup>

A reduction in office visits, elective procedures, and non-COVID-19 HCRU due to shelter-in-place orders and patient avoidance of health care settings has financially strained hospitals, primary care providers, and independent specialty practices.<sup>41,42</sup> Insurance providers have experienced increased administrative burden due to inquiries from members regarding coverage and access to care, the need to modify benefits to include telehealth or equalize out-of-pocket costs for nonnetwork providers, and training and resource development on procedures related to COVID-19 and new billing codes.<sup>43</sup> Insurers also anticipate that employment loss will increase individual

an increased volume of ED visits related to respiratory symptoms and infectious disease contact, the overall volume of ED visits in the United States decreased by 30% to 50% in 2020 vs 2019, with the sharpest decline in March and April 2020 (early pandemic period).<sup>51-53</sup> Regional declines were associated with increasing COVID-19 case-load.<sup>51,52</sup> Although the number of ED visits for nonspecific chest pain and acute myocardial infarction decreased, emergency calls and ED visits for cardiac arrest increased.<sup>49,52</sup> The Adventist Health Lodi Memorial health system reported that all patients who experienced a stroke and were admitted to the ED in March 2020 arrived too late for administration of tissue plasminogen activator, an important factor in the recovery of patients experiencing ischemic stroke.<sup>49</sup> These observations suggest that patients may be waiting too long to seek care due to concerns over visiting health care facilities during the COVID-19 pandemic.

Additionally, some patients may have difficulty accessing or adapting to virtual health platforms and telemedicine because of limited digital literacy or infrastructure,<sup>54,55</sup> which can lead to delayed or missed follow-up visits following NMS. These concerns may cause patients who experience new or worsening disease symptoms or reactions to medication after NMS to delay seeking care, which can lead to a higher risk of negative health outcomes.

The pandemic has created financial strain for many patients, which may be exacerbated by NMS. Business closures and reduced operating capacity to accommodate social distancing have led to increased unemployment and reduced working hours.<sup>56</sup> The US unemployment rate rose 10.3 percentage points between March and April 2020, and approximately 1 million new unemployment claims were filed weekly between late March and September 2020.<sup>57,58</sup> Although unemployment has decreased, the rate as of September 2021 remained above the prepandemic rate in February 2020 (4.8% vs 3.5%).<sup>56</sup> In addition to loss of income, patients may also lose health insurance and experience delays in finding new coverage, particularly in states that did not participate in Medicaid expansion.<sup>59</sup>

The pandemic may impose further financial burden on patients required to switch medications if they experience reduced working time or additional expenses due to illness, caring for others who are ill, quarantine after contact with an infected person, or changing childcare needs.<sup>60,61</sup> Additionally, patients or their dependents may face substantial health care costs associated with testing, treatment, or hospitalization for COVID-19, as well as costs from potential long-term complications or new or worsening mental health conditions stimulated by the pandemic environment.<sup>58,60,62</sup>

Overall, loss of income, loss of insurance, or limited insurance coverage may leave patients unable to afford medications or cause them to delay seeking care, which can lead to exacerbations of chronic conditions or more severe outcomes of new conditions, and delayed treatment and management may result in higher long-term health care costs.<sup>63</sup> The increased health care costs associated with NMS in the pandemic setting can impose additional financial strain or result in patients' inability to afford their medication.

## Ensuring Continuity of Care for Patients

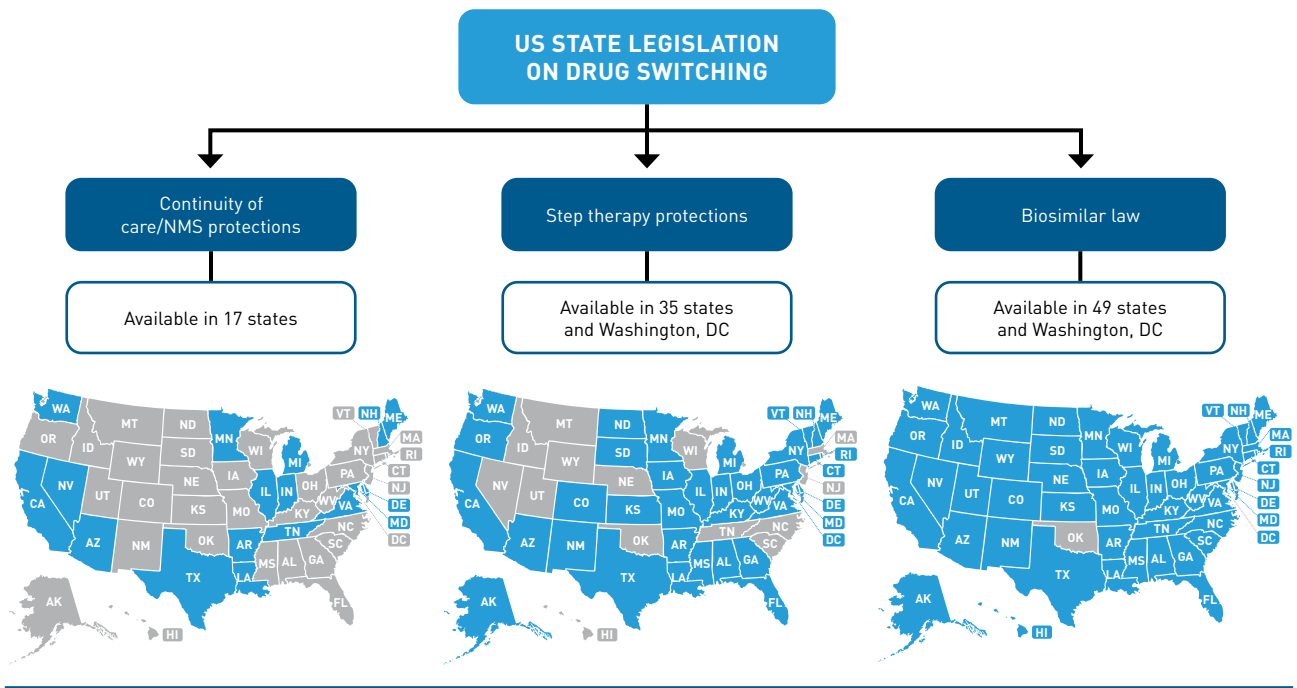
HCPs and support staff should play a role in advocating for consistent and continuous treatment for their patients from diagnosis to prescription fulfillment. It is therefore important for HCPs to be familiar with continuity of care legislation, appeals and medical exception processes, and manufacturer assistance programs to ensure that patients continue to receive the therapy they need.

Federal and state governments have implemented continuity of care legislation to prevent automatic substitution of one medication with another by formularies and pharmacies (Figure 5<sup>64</sup>). As of December 2020, 49 states and Washington, DC, had legislation regulating automatic substitution of a biosimilar for a reference drug, which may entail requiring that the biosimilar be FDA approved as interchangeable with the reference drug, providing HCP autonomy in prescribing a biosimilar and/or indicating that substitution cannot be made, and requiring HCPs and patients to be notified of the switch.<sup>64</sup> Forty states have legislation restricting the use of step therapy or fail-first protocols,<sup>64</sup> protecting patients from switches to a less-expensive generic or biosimilar in the event of formulary changes. Only 18 states have legislation that places restrictions on NMS in general, most of which are limited to HCP and patient notification and/or extended coverage for the original medication for a limited time. However, state legislation does not apply to self-funded benefit plans, which are regulated under the Employee Retirement Income Security Act (ERISA).<sup>65</sup> The Safe Step Act was introduced into the US Senate in February 2021 to align state actions with ERISA.<sup>66</sup>

When lack of or limited coverage will prevent or delay patients' access to treatment, HCPs can submit formulary exceptions or prior authorization requests. Most prior authorization requests are ultimately approved, with an approximate 63% to 93% success rate on first submission and a 65% to 82% success rate on appeal.<sup>67-69</sup> Use of a centralized pharmacy intervention in the prior authorization and appeals processes can increase acceptance rates and reduce delays in prescription fulfillment.<sup>67,68</sup> Drug manufacturers may provide other resources to help patients and HCPs navigate changes in treatment coverage and ensure continuity of care, including supporting literature, appeals kits, and assistance with prior authorizations or formulary exceptions. In addition, many drug manufacturers offer patient assistance programs and co-pay cards for patients who need to remain on their current medication but face insurance-related or other financial obstacles.

In the context of the COVID-19 pandemic, it is especially important for HCPs to advocate for consistent, continuous treatment for their patients to avoid the potential for disease exacerbations, medication-related adverse effects, and increased HCRU and medical costs. If NMS is unavoidable or necessary due to medication shortages, HCPs should encourage patients to continue their routine appointments and treatment administration and to seek care when they develop new or worsening symptoms or adverse effects. To build patient confidence in the safety of health care settings during the COVID-19 pandemic, it is important for HCPs to communicate clear information

**FIGURE 5. US States With Legislation Regulating NMS<sup>44</sup>**



NMS, nonmedical switching.

about infection risk, protective measures, cleaning procedures, and resource availability. Direct, preemptive communication from providers and health care facilities about available resources and services, precautions in place to keep patients safe, and knowledge of what to expect when visiting the facility for care can help relieve anxiety for patients considering delaying care.<sup>49</sup> Expanding access to telemedicine can help ensure patients have access to their HCP and sufficient follow-up appointments.<sup>52</sup>

**Conclusions**

NMS can lead to loss of disease control, new or more severe medication-related adverse effects, and increased HCRU and patient costs. NMS can also increase administrative and financial burdens for HCPs and payers. The COVID-19 pandemic has broadly affected the physical, psychological, and financial health of society, and the long-term implications are uncertain. Navigating the effects of the pandemic may be especially challenging for patients with chronic illness who already experience substantial psychosocial and financial burdens and may be at increased risk of SARS-CoV-2 infection or more severe COVID-19 complications.

HCPs should play an active role in advocating for continuous treatment for their patients and should be familiar with their states' continuity of care legislation, appeals and medical exception processes, and manufacturer assistance programs to ensure patients continue to receive the therapy they need. However, it is important to acknowledge the high rate of burnout among HCPs that has been

exacerbated by the pandemic and the additional work that NMS adds to their administrative and mental load. The decision to switch treatments should be the result of shared decision-making between HCPs and patients to achieve the best clinical and quality-of-life outcomes and ensure optimal HCRU. ■

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**Authorship Information:** Concept and design (JFM, SP, SH, EY, DP, ML); acquisition of data (AWA); analysis and interpretation of data (JFM, AWA, SH, EY, DP, ML); drafting of the manuscript (SP, SH, EY, DP); critical revision of the manuscript for important intellectual content (JFM, AWA, SP, SH, EY, DP, ML); obtaining funding (EY, DP); administrative, technical, or logistic support (JFM, AWA, EY, DP); and supervision (SH, EY, DP).

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