

# Shared Clinical Decision Making for Vaccines

Challenges and  
Implications for  
Vaccine Awareness,  
Administration,  
and Uptake



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## EXECUTIVE SUMMARY

**WHEN VACCINES ARE RECOMMENDED FOR USE IN THE U.S.**, one of three recommendation types are typically utilized – routine, catch-up, or shared clinical decision-making (SCDM). For vaccines that receive a SCDM recommendation, there are often reported downstream implementation implications and interconnected hurdles across providers, patients, vaccine management, and reimbursement. Further, SCDM recommendations may present additional challenges for underserved populations and undermine efforts to facilitate broad vaccine access.

Key challenges and considerations associated with SCDM vaccine recommendations on vaccine awareness, administration, and uptake include:



**While shared clinical decision-making (SCDM) vaccine recommendations are not inherently problematic**, the implications of SCDM can create complexities and hurdles that impact providers, patients, administration, reimbursement, and ultimately uptake



**SCDM recommendations can further complicate patient-provider communications**, requiring increased time and resources from providers as they balance the need to provide a comprehensive recommendation while addressing diverse beliefs, varying health literacy, and increasingly widespread mistrust and misinformation.



**SCDM emphasizes patient responsibility**, placing increased importance on health literacy, culturally competent resources, and consistent healthcare touchpoints.



**SCDM adds complexity to vaccine management**, impacting forecasting, administration, and creating financial and logistical barriers that could in turn hinder vaccine uptake.



**Current reimbursement models do not fully account for the complexities** or additional resource requirements associated with SCDM vaccines, and as a result integration of SCDM may be financially challenging for many vaccine administrators.



**The challenges associated with SCDM impact many patient populations**, but may be especially detrimental to underserved groups, which in turn stands to exacerbate existing health disparities.

# Background on Shared Clinical Decision-Making

**IN THE U.S., TWO FEDERAL REGULATORY BODIES** – the Food and Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC) – approve and recommend vaccines for pediatric, adolescent, and adult populations to help prevent and control infectious diseases.<sup>1</sup> Following FDA approval and before coming to market, CDC's Advisory Committee on Immunization Practices (ACIP) develops vaccine recommendations informed by many factors including disease epidemiology, vaccine safety and efficacy, population-specific considerations, public health impact, and health equity, among others.<sup>2</sup> The CDC then finalizes the annual U.S. childhood and adult immunization schedules based on ACIP's recommendations.

ACIP typically uses one of three recommendation types when developing a vaccine recommendation<sup>3</sup>:

- 1 Routine (including age- or risk-based):** A recommendation that a vaccine be administered to everyone in a particular age group or risk category.
- 2 Catch-Up:** A recommendation that a vaccine be administered to individuals who missed a vaccine when they were younger, ensuring they are up to date with the current immunization schedule. This type of recommendation can also be made when a new vaccine is approved by FDA, as a means to ensure that individuals who either were not previously vaccinated against a particular disease, or who received an earlier version of the vaccine, can receive the new vaccine to benefit from its improved protection.
- 3 Shared Clinical Decision-Making (SCDM):** A recommendation that the decision to vaccinate be made jointly by the healthcare provider and the patient with consideration for the individual benefits and risks.



**SHARED CLINICAL DECISION-MAKING OR SCDM** is a relatively new type of recommendation and was introduced during a June 2019 ACIP meeting as the next iteration of what was previously known as a “Category B” or permissive recommendation.<sup>4</sup> As delineated above, unlike a vaccine with a routine recommendation, vaccines with SCDM recommendations are not administered to all patients within a specified population but rather rely on patient-provider discussions and are administered to individuals based on several factors, including individuals’ characteristics and preferences and providers’ clinical discretion. ACIP may make a SCDM recommendation when there is still individual-level benefit to vaccination, but there is uncertainty about the benefit of a broad recommendation.<sup>5</sup>

Currently, five vaccines have received a SCDM recommendation, as noted in Table 1.<sup>6,7</sup> In recent years, the number of vaccines with SCDM recommendations has increased—two of the five vaccines with a SCDM recommendation have been recommended within the past two years. Notably, 75% of the vaccines with SCDM recommendations impact older adult populations.

**TABLE 1 VACCINES WITH SCDM RECOMMENDATIONS**

Vaccine and Indication	Year SCDM Recommendation Received
<b>Respiratory syncytial virus (RSV) vaccination</b> for adults 60 years and older	2023
<b>Pneumococcal conjugate vaccination (PCV20)</b> for adults aged 65 years and older who have completed the recommended vaccine series with both PCV13 (at any age) and PPSV23 (administered at age ≥65 years)	2023
<b>Human papillomavirus (HPV) vaccination</b> for adults aged 27 – 45 years	2019
<b>Meningococcal B (MenB) vaccination</b> for adolescents and young adults aged 16 – 23 years	2015
<b>Hepatitis B (HepB) vaccination</b> for adults aged 60 years and older with diabetes mellitus	2011

Within CDC, SCDM remains a largely undefined concept and the implications of implementing this type of recommendation are nuanced and often lead to additional complexities and hurdles. As a result, there may be multifaceted and interconnected impacts on providers and patients, administration, reimbursement, and ultimately vaccine uptake.<sup>8,9,10</sup> Importantly, while SCDM recommendations can present challenges for a wide range of patient populations, the obstacles associated with SCDM may be especially detrimental to underserved groups, exacerbating health disparities and undermining efforts to ensure broad vaccine access.

The issue brief that follows examines the challenges and considerations associated with SCDM vaccine recommendations for providers, patients, vaccine management, and reimbursement, and touches on the intersection between SCDM challenges and health disparities in each of these contexts.

# Challenges Related to SCDM Recommendations for Vaccines



## PROVIDERS

**HEALTHCARE PROVIDERS (HCP)**—including those in physician offices and at the pharmacy—play a critical role in providing vaccination services to their communities, and data show that communication between HCPs and patients is one of the most important factors shaping individuals’ trust and openness to vaccination.<sup>11,12</sup> However, initiating and navigating conversations around vaccines, especially those not routinely recommended, can be challenging and time-consuming and SCDM can present numerous challenges for providers.<sup>13</sup> This has become especially true in the context of the COVID-19 pandemic, as decisions about vaccinations have become increasingly personal and politicized.<sup>14</sup> A SCDM recommendation can make patient-provider communications about vaccines even more complex, requiring increased time and resources from providers as they balance the need to provide comprehensive patient education with limited consultation time, resource constraints, diverse cultural beliefs, varying health literacy levels and increasingly widespread dissemination of misinformation and mistrust in vaccines. All of these factors complicate the decision-making process and can stand in the way of providers’ ability to offer strong, personalized and effective vaccine recommendations.

### Lack of Standard Guidance Can Complicate Decision-Making & Implementation

Despite the myriad factors that can impact, complicate or even prevent the SCDM process for providers, no standard guidelines or resources currently exist to support providers in these assessments and conversations. In a survey of over 600 providers on attitudes about, and experience with, SCDM recommendations the vast majority of respondents indicated that when ACIP makes a SCDM recommendation, they would benefit from specific

talking points to help guide patient discussions regarding vaccination.<sup>15</sup> Yet, available resources are limited and – given the range of challenges touched on in the previous section –without standard guidance or educational materials, providers may struggle to effectively communicate the benefits and risks of vaccines, leaving room for potential misunderstandings, incomplete information and patient difficulty with decision-making.

The lack of a standardized approach to SCDM provider-patient conversations complicates the decision-making process for both providers and patients, and can lead to implementation challenges and, in turn serve as a potential barrier to patient vaccine access and uptake.<sup>16</sup> This may be particularly detrimental for communities with higher exposure to health disparities. For example, while standardized guidance could theoretically be developed to account for patients of all health literacy levels and could help ensure cultural competency was addressed, without standard guidance, patients with lower levels of health literacy or diverse cultural backgrounds may not be able to fully understand their options which could lead to suboptimal decision-making among a group that may already be more vulnerable to access barriers and poor health outcomes. As such, the lack of standard guidance demonstrates just one way SCDM can exacerbate health disparities and undermine progress related to more equitable access and uptake.

### Additional Time & Resource Requirements Not Accounted for Within Current Care Frameworks

Because patient-provider conversations on SCDM vaccines are complex and providers lack a set of standard guidelines for these exchanges, facilitating a productive discussion can also be time intensive. In a survey of family physicians and general internists, upward of 90% of respondents said they agreed

that SCDM requires more time with patients than routine recommendations.<sup>17</sup> Unfortunately this extra time is not always available and because providers may need to cover multiple topics during an appointment—depending on patient age and the frequency of healthcare touchpoints—time dedicated to vaccination may be limited or come at the expense of other important issues.<sup>18,19</sup> A recent study examining pneumococcal PCV13 vaccine uptake rates among Medicare beneficiaries following ACIP’s 2019 vote to recommend SCDM for PCV13 among immunocompetent adults  $\geq 65$  years demonstrates the potential real world impacts of this dynamic. The study found the following changes in vaccine uptake following this recommendation change<sup>20</sup>:

- Among immunocompetent beneficiaries PCV13 uptake declined by up to 23%.
- Additionally, among high-risk, immunocompromised beneficiaries, vaccine uptake also declined by up to 21%, despite PCV13 maintaining a routine recommendation for this population.

In short, these data points indicate that for healthcare providers caring for patients with comorbid or other chronic conditions, navigating complex and competing health concerns may truncate discussion on available vaccines not routinely recommended and may even have impacts on guidance and recommendation for vaccines with routine recommendations.<sup>21</sup> In some cases, a SCDM vaccination decision may also

occur after a number of conversations and potentially with different providers in different settings, including physician offices, pharmacies, and public or rural health clinics. Once again, this situation is particularly relevant for individuals living in medically underserved areas, those with lower health literacy, and/or those who have limited access to transportation or a regular healthcare provider.<sup>22</sup>

In addition to reported challenges navigating patient conversations and assessing risk factors, the vaccine landscape is also evolving, requiring providers to dedicate time and resources to monitor and respond to recommendation changes and the introduction of new vaccines. And while some vaccinators may have greater access to the latest vaccine guidance, decision-making aids, and educational materials, others’ access may be more limited. This dynamic environment further complicates the already nuanced process of shared clinical decision-making between providers and patients.<sup>23</sup> As a result, SCDM recommendations may be inconsistently implemented across practices.<sup>24</sup> This barrier is illuminated in early prescribing practices for MenB vaccines. Two years after MenB vaccines received a SCDM recommendation, only 7% of surveyed healthcare providers indicated that they prescribed MenB vaccines consistent with ACIP recommendations compared to 77% for MenACWY.<sup>25</sup> Because HCPs can interpret and implement SCDM recommendations in their clinical practices differently, some individuals might be presented with the opportunity for vaccination while others are not.<sup>26</sup>





## SPOTLIGHT: MENINGOCOCCAL VACCINES

**Invasive Meningococcal Disease (IMD)** is a relatively uncommon but serious and potentially life-threatening infection. In the U.S. rates of IMD peak in adolescents and young adults, with more than 90% of cases caused by 5 serogroups – A, B, C, W and Y).

Today, three vaccines are available to provide protection against IMD:

- 1 MenACWY:** A quadrivalent vaccine introduced in 2005; Provides protection against 4 of the 5 most common serotypes (A, C, W, and Y). **ACIP recommendation: Routine for all healthy adolescents**
- 2 MenB:** Introduced in 2015; Provides protection against meningococcal serogroup B. **ACIP recommendation: SCDM for healthy adolescents and young adults (16-23 years of age)**
- 3 MenABCWY:** A pentavalent vaccine introduced in 2023; Provides protection against all 5 serotypes (A, B, C, W, Y). **ACIP recommendation: Option for individuals 10 years of age and older who are getting MenACWY and MenB vaccines at the same visit**

Despite the fact that both vaccines provide valuable protection against the serogroups that most commonly cause IMD in the U.S., uptake is vastly different between the two. As of 2022, only 11.9% of eligible adolescents received a complete MenB (SCDM recommendation) vaccination series compared to 60.8% of adolescents who completed their MenACWY (routine recommendation) vaccination series.

Research has shown that this significant discrepancy in uptake between the two vaccines is likely—in part—related to MenB's SCDM recommendation. Studies examining provider interpretation of MenB's vaccination recommendation and implementation, have identified HCP confusion and lack of uniform guidance related to the vaccine's SCDM recommendation as a contributing factor to the MenB's low uptake. Additionally, a nationally representative survey of HCPs found that only 51% of pediatricians and 31% of family practitioners reported "always or often" discussing the MenB vaccine with eligible patients.

#### SOURCES:

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8545751/>

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9962690/>

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7227692/>

**Research has shown that this discrepancy in uptake between the two vaccines is likely – in part – related to MenB's SCDM recommendation.**

# When providers lack the time or understanding to counsel patients on SCDM vaccines, there are resulting missed opportunities to vaccinate

According to a well-established body of research, a strong provider recommendation in a wide range of settings, coupled with onsite administration, is shown to promote vaccination.<sup>27</sup> In a study on influenza vaccination among U.S. adults, those who reported that a provider both recommended and offered a vaccine had significantly higher vaccination coverage (66.6%) compared to those who received a recommendation but not a vaccine (48.4%) and those who received neither a recommendation nor offer (32%).<sup>28</sup> When providers lack the time or understanding to counsel patients on SCDM vaccines, there are resulting missed opportunities to vaccinate. This situation also introduces the potential for provider bias to influence recommendation. For example, according to findings from a 2017 survey, healthcare providers were more likely to prescribe MenB vaccination if they had a higher number of patients who they perceived as understanding the difference between MenACWY and MenB vaccines.<sup>29</sup> In this same survey, patients who received MenB vaccine were more likely to be male, non-Hispanic White, and living in a campus dormitory or other shared space.<sup>30</sup>

## Importance of Consistent Patient Interactions & Access to Full Medical History Can Contribute to Recommendation Complexities

SCDM recommendations also require providers to assess a patient's full spectrum of risk factors, among other considerations, before aligning on whether to move forward with vaccination. As noted by the CDC, "the decision about whether or not to vaccinate may be informed by the best available evidence of who may benefit from vaccination; the individual's characteristics, values, and preferences; the health care provider's clinical discretion; and the characteristics of the vaccine being considered."<sup>31</sup>

Assessing these elements may be particularly challenging if patients' complete medical records are not available. In a 2022 survey on providers' attitudes toward and knowledge of pneumococcal vaccines, providers recognized the value of pneumococcal vaccines.<sup>32</sup> However, a significant proportion of survey respondents reported that the nuances of the recommendations, which varied based on patients' vaccination history and underlying medical conditions, posed challenges to interpretation and implementation.<sup>33</sup> This issue is especially pertinent in the pharmacy setting since Medicare Part D vaccines, like respiratory syncytial virus (RSV) vaccines, are not usually offered in physician offices. Unfortunately, pharmacists' access to a patients' full medical history is often even more limited than providers' access. If pharmacists cannot appropriately evaluate patients' medical records, individuals may experience issues accessing recommended vaccines.

The increased importance of consistent and regular interactions with patients and access to full medical histories that is associated with SCDM can be particularly burdensome for underserved groups. A large body of research shows, for example, that due to a wide range of systemic barriers Black, Hispanic and American Indian and Alaska Native populations are less likely than White Americans to have a usual source of care that they see regularly for preventive services (e.g. primary care provider).<sup>34</sup> Similarly, compared to middle and higher-income groups, low-income Americans are also less likely to have a usual source of care.<sup>35</sup> Further, a 2022 study evaluating healthcare access in low-income settings, found that adults in low-income communities have greater access to pharmacies than to physicians offices, which means this population may be more likely to access preventive services at non-provider





locations.<sup>36</sup> Given these realities, vulnerable groups may experience even greater barriers related to SCDM which in turn could further contribute to health disparities and could compromise efforts aimed at improving health equity.

### **Greater Variability in Recommendations May Exacerbate Social Determinants of Health-Related Barriers**

By nature of the recommendation, navigating SCDM is personal and variable. Lack of standardization and consistency in care practices, increased time and resource requirements, and complex decision-making can shape if and how providers recommend vaccines through SCDM. These factors may also contribute to health inequities. In a systematic review on the impact on social determinants of health (SDOH) on meningococcal vaccination, lower MenB coverage rates were reported among Black adolescents compared to White adolescents. Furthermore, MenB series completion rates were lower among adolescents with Medicaid coverage. Individuals living in neighborhoods with a median income >\$100,000 were more likely to receive MenB vaccine compared to those in neighborhoods where the median income is <\$20,000.<sup>37</sup> Successful vaccination programs rely not only on availability of vaccines but also on strong implementation rooted in clear recommendations and strategies.



## **PATIENTS**

**IN ADDITION TO PROVIDER RESPONSIBILITIES,** SCDM also centers patients in the vaccine decision-making process. While not conceptually problematic, accessing and receiving SCDM vaccines does assign more responsibility to patients, placing increased importance on individual patients' baseline health literacy and consistent healthcare touchpoints. These considerations may impact vaccine uptake especially among the most vulnerable and underserved populations.

### **Shift of Greater Responsibility to Patients without More Educational Resources Can Lead to Disparities in Understanding & Uptake**

As previously outlined, providers may not always have the tools needed to appropriately recommend SCDM vaccines during healthcare visits. In the absence of standard implementation guidelines, some providers may facilitate discussions on SCDM vaccines while other may not. In these instances, patients or parents/caregivers of patients are increasingly responsible for raising interest in vaccination. However, variable health literacy or vaccine awareness may preclude those open to vaccination from the opportunity to receive a vaccine. This consideration is not inconsequential – in the U.S., an estimated 80 million individuals have

limited health literacy.<sup>38</sup> Even if individuals are familiar with healthcare information, they might not always be well-informed on the latest available vaccines.

In the case of MenB vaccination, two years after receiving a SCDM recommendation, over 80% of parents were still not aware of the vaccine's availability.<sup>39</sup> Findings from this survey attribute the disparities in knowledge of MenB vaccines to parental confusion, race/ethnicity, lack of HCP recommendation, and socioeconomic status.<sup>40</sup> In an analysis of parents who were aware of MenB vaccine compared to those who were not, parents of White, non-Hispanic adolescents were significantly more aware of MenB vaccine.<sup>41</sup> Under the assumption that none of the parents who were unaware of the vaccine had received an HCP recommendation and had their adolescent vaccinated, an estimated 70 – 80% of 16-to-17-year-olds missed opportunities to receive the MenB vaccine.<sup>42</sup>

### Potential for Lower Uptake Due to Increased Importance of Consistent Healthcare Touchpoints

Another potential complication to SCDM vaccine access is proximity to and relationship with a healthcare provider. According to a 2023 report from the National Association of Community Health Centers (NACHC), nearly a third of Americans face barriers accessing primary care<sup>43</sup>. Since 2014, the number of medically disenfranchised individuals has nearly doubled and over half of this population has an income below 200% of the Federal Poverty Level.<sup>44</sup> A greater proportion of adults who do not report having a personal doctor or healthcare provider are also from racial / ethnic minority populations. As of 2022, 30.4% of Hispanic adults, 20.3% of Asian/Native Hawaiian or Pacific Islander, 20% of American Indian/Alaska Native (AI/AN) adults, and 12.8% of Black adults report not having a personal doctor.<sup>45</sup>

If patients are unable to reliably access primary care, opportunities for vaccination—especially those necessitating SCDM—are considerably diminished. Beyond accessing a primary care provider, patients also report higher satisfaction if they see the same HCP over time.<sup>46</sup> Continuity of care has been associated with improved health and utilization of preventive services.<sup>47</sup> Fostering trusted patient-provider relationships is demonstrably important to vaccine uptake and arguably more critical when counseling is required for SCDM vaccines. Ensuring culturally competent care – engaging the

social, linguistic, and cultural needs of all patients – is also important in the context of SCDM vaccines. Because these recommendations are more nuanced, providers need to understand patient risk factors as well as facilitate productive discussions with patients on individual-level vaccination considerations. Accomplishing this evaluation is made considerably more challenging if patients do not receive appropriately tailored care. In a study on influenza vaccination coverage, individuals who were “always” or “most of the time” treated with respect, given easy-to-understand information, asked their opinions about their care, and seen by providers who shared or understood their culture had higher odds of influenza vaccination.<sup>48</sup> These learnings demonstrate the importance of culturally competent care across healthcare encounters and especially in the vaccine decision-making process.

The effectiveness of a SCDM recommendation is dependent on a number of variable factors, including patient access to an HCP, provider and patient familiarity with the vaccine, and effective provider-patient communication. When these factors are not established, individuals who are eligible and could benefit from vaccination are likely not receiving vaccination services.



## VACCINE MANAGEMENT

**SCDM ADDS A LAYER OF COMPLEXITY** to vaccine management that can significantly impact forecasting and administration. These challenges can present financial and logistics barriers that can disincentivize the stocking of SCDM vaccines, which in turn can lead to referrals to secondary sites, and even reduced recommendations, both of which ultimately have the potential to hinder uptake rates. Further, SCDM recommendations are often not supported by current electronic health record (EHR) systems making it more difficult for vaccine administrators to assess vaccination opportunities and to take and understand drivers of vaccine uptake.

### Uncertainties Around Eligibility & Uptake Can Contribute to Added Forecasting Challenges

As well-established and previously detailed, provider-driven vaccine recommendations are a key predictor of vaccine uptake; however, providers are less likely to recommend vaccines that are not stocked in their

# Vaccines with SCDM recommendations may add an additional layer of vaccine management and forecasting complexity

office.<sup>49</sup> When deciding which vaccines to stock, providers often cite financial considerations, such as reimbursement and costs associated with purchasing and maintaining vaccine inventory.<sup>50</sup> In a survey of individuals involved in vaccine stocking decisions, cost of purchasing vaccine stock, maintaining vaccine inventory, and lack of adequate reimbursement were cited as the most important factors shaping vaccine stocking decisions.<sup>51</sup> Vaccines with SCDM recommendations may add an additional layer of vaccine management and forecasting complexity. For example, in this same survey, the most commonly stocked vaccine was influenza at 97% while the stocking rate for MenB was just 39%.<sup>52</sup>

One potential repercussion associated with inadequate vaccine stock is losing patient vaccination opportunities. If a vaccine is not stocked at the provider's office, depending on the vaccine and coverage type, the patient is likely referred to a retail pharmacy for vaccination. This second site of care can often lead to a lack of follow through and lower vaccine uptake.<sup>53</sup> There are many reasons why individuals interested in vaccination do not always pursue vaccine services when referred to a pharmacy, including transportation issues, scheduling conflicts, inability to take more time off work, etc.<sup>54</sup> This issue can be particularly impactful for underserved or rural populations who may have additional geographic barriers and social determinants of health that make having two separate appointments and sites of care especially burdensome.

## Limited Technology to Support SCDM Can Exacerbate Monitoring & Surveillance Issues

SCDM vaccines can also complicate vaccine management systems and ultimately the ability to accurately monitor, track and assess uptake rates. In most practices, providers leverage electronic health records (EHR) to help capture patients' medical history, demographic information, immunizations, and lab

reports. EHRs can also support vaccine forecasting software which is an automated process that flags when a patient is recommended to receive a vaccine.<sup>55</sup> However, because SCDM vaccines are not routinely recommended, many healthcare providers report challenges in utilizing vaccine reminder systems within EHRs. A national survey of general internal medicine physicians and family physicians found that only 38% of respondents' EHR systems displayed SCDM recommendations as "recommended", while 23% indicated that their EHR system does not display a recommendation for SCDM vaccines. Further, only 3% reported receiving a specific prompt to facilitate a SCDM conversation.<sup>56</sup> If decision software is not appropriately tailored to support SCDM recommendations, providers may not be prompted to discuss available vaccines with their patients, leading to potential missed vaccination opportunities.

## Potential Barriers to Assessing Vaccine Awareness & Acceptance Due to Inconsistent Recommendations & Tracking

Beyond issues leveraging EHR systems, SCDM vaccine recommendations also create challenges in understanding drivers of vaccination. There are many variables that influence vaccine uptake and SCDM can make it even more difficult to identify an individual's rationale for getting vaccinated – or not. In some instances, individuals may not know about a vaccine and/or a provider may not have facilitated discussion about a vaccine they may be eligible for and benefit from. Other times, individuals may choose not to get vaccinated despite receiving a recommendation. When all these considerations are taken together, SCDM recommendations may contribute to an even more opaque understanding of vaccination drivers. As efforts are ongoing to close the vaccination gap for populations facing healthcare disparities, challenges tracking and understanding vaccine uptake may be especially impactful for already underserved groups.



## REIMBURSEMENT

**CURRENT REIMBURSEMENT MODELS** and mechanisms are not fully designed or equipped to account for the additional time, resources and complexities associated with SCDM vaccines. As a result, vaccine administrators are often faced with significant challenges related to reimbursement and infrastructure when administering vaccines with this recommendation. A lack of adequate and appropriate incentives for SCDM means that integration of SCDM into provider practices and other vaccination settings may be financially challenging. These issues stand to impact patients from all demographic groups but—as is often the case—gaps in reimbursement can be especially pronounced in settings that serve lower-income and underserved populations and therefore these challenges may be particularly burdensome for already vulnerable populations.

### **Current Provider Reimbursement Models Do Not Adequately Account for Additional Time & Resources Required**

While reimbursement rates vary significantly across insurance plan types, nearly all insurance plans currently provide some level of reimbursement for vaccine acquisition (i.e., cost of the vaccines) and for vaccine administration. That said, given the relatively recent introduction of SCDM for vaccines, the models currently in place for vaccine reimbursement were not designed to accommodate and adequately account for the additional resources and time SCDM requires of providers, which often complicates determinations around coverage and payment.<sup>57</sup>

Unlike the administration of vaccines with a routine recommendation, effective administration of SCDM vaccines requires providers to undertake more extensive review of medical records, develop tailored recommendations for each patient, and engage in potentially time intensive explanation, discussion and counseling related to these recommendations. Further—as outlined in previous sections—due to the lack of standardization and highly individualized and variable nature of SCDM, in order to facilitate productive and informed SCDM with patients, providers must allocate additional resources toward staff training and educational materials to ensure

they are staying up to date and have the tools needed to make appropriate recommendations and provide thorough counseling. The additional time and resources associated with the SCDM process, for the most part, is not covered through current reimbursement models, which are typically limited to administration and fail to account for counseling, consult or training and education.<sup>58</sup>

### **Infrastructure & Reimbursement Challenges Can Be Especially Complex in Pharmacy Settings**

The lack of compensation for the additional time required of vaccine administrators to make a strong recommendation for a SCDM vaccine can be especially pronounced in the pharmacy setting. In recent years as authority expanded in the wake of the COVID-19 pandemic, pharmacists' role in vaccine administration has expanded significantly and today, a large majority of adult vaccines are administered in pharmacy settings.<sup>59</sup> According to an IQVIA analysis of 2021-2022 claims data<sup>60</sup>:

- Upwards of 90% of COVID-19 vaccinations were administered at pharmacies,
- Between 60-70% of flu vaccines and 40-50% of pneumococcal vaccines administered during respiratory illness season took place in a pharmacy setting, and
- The shingles vaccine showed a similar trend, with a large majority of administration taking place at the pharmacy level.

Overall, this trend represents a positive shift as it increases vaccine accessibility and in turn stands to improve uptake. This increased accessibility can be especially meaningful among lower-income populations, as recent research shows that families with lower household incomes have greater access to pharmacies than to physician practices.<sup>61</sup> However, when a pharmacist is administering a vaccine with a SCDM recommendation it can be particularly challenging given that—compared to primary care providers who serve as a “usual source of care”—pharmacists' access to a patient's comprehensive medical history is limited and while in some cases pharmacists have more frequent interactions with patients than other HCPs, these interactions are often shorter and less comprehensive.<sup>62</sup> These realities can make facilitating a SCDM discussion even more time and resource intensive, as in addition to reviewing

# Without appropriate incentives, providers may find SCDM financially challenging, hindering the integration of SCDM into their practices and care models

medical records, pharmacists often first must collect a patient's history.

In addition to insights and relationships with patients often being more limited, pharmacy settings also typically lack the infrastructure needed to support detailed patient consultations, and vaccine reimbursement rates paid to pharmacies can differ—and often be lower—than the rates paid to provider offices, especially in the context of Medicaid.<sup>63</sup> For instance, a 2024 research study examining the impact of reimbursement rates on uptake of flu vaccines, found that in many states Medicaid reimbursement rates to pharmacies barely cover the cost of the vaccine.<sup>64</sup> Considering Medicaid serves low-income Americans and that among lower-income populations vaccines are more accessible in pharmacy settings, these reimbursement gaps could potentially lead to exacerbation of health inequities among communities already facing disparate impacts related to health disparities.<sup>65,66</sup>

## Unique Reimbursement Mechanisms for Federally Qualified Health Centers (FQHCs) Can Create Barriers for Some of the Most Underserved Populations

Even more potential reimbursement gaps arise within the context of FQHCs, which are federally funded nonprofit health centers that provide care within medically underserved areas and populations.<sup>67</sup> According to the most recent data, approximately half of all patients who visit FQHCs are insured by Medicaid.<sup>68</sup> While providers and pharmacies are typically reimbursed for individual services provided, many states' Medicaid programs use what is known as the Prospective Payment System (PPS) to reimburse FQHCs. Under this system Medicaid pays a single bundled rate for each patient visit that is intended to cover the costs

of all services and supplies associated with the visit.<sup>69</sup> PPS is meant to account for vaccine expenditures in the calculation of its rate, but in practice the payment for the full visit is sometimes lower than even the amount spent to acquire the vaccine.<sup>70</sup>

While the lack of adequate reimbursement for vaccines within FQHCs is already challenging when considering vaccines with routine recommendations, this payment disparity can present even more obstacles for vaccines with a SCDM recommendation, given the increased burden on time and resources that is associated with SCDM vaccines. This is particularly concerning when considering the population that FQHCs serve. According to the latest data from the National Association of Community Health Centers, of the patients that FQHCs serve, 90% have low-income status, 41% are rural residents and 64% are members of racial and/or ethnic minority groups.<sup>71</sup>

As detailed in the above sections, without appropriate incentives, providers may find SCDM financially challenging, hindering the integration of SCDM into their practices and care models. This is more likely in pharmacy and FQHC settings where the reimbursement gaps are higher and the extra time and resources that SCDM requires may be especially burdensome. Unfortunately, these settings are also more likely to serve underserved groups. As such, once again, it is clear that while reimbursement challenges related to SCDM have the potential to impact all patient populations, the impact of these challenges could be more burdensome for underserved groups who are less likely to have a regular point of care and are more likely to be vaccinated in a setting where SCDM is financially onerous and therefore not fully incorporated into patient care.<sup>72,73</sup>

## CONCLUSION

**VACCINES ARE ONE OF THE MOST IMPORTANT PUBLIC HEALTH INTERVENTIONS CURRENTLY AVAILABLE,** helping to protect individuals against adverse outcomes – including death—associated with vaccine-preventable diseases.<sup>74</sup> However, the benefits of vaccination can only be fully realized when vaccines are available, accessible, and administered to all eligible populations. The COVID-19 pandemic brought this reality to light and underscored not only the benefits of vaccines but also the wide range of complexities, nuances and challenges that impact vaccine awareness, administration and uptake. Over the past several years, the public health community has observed the impact of age, geography, socio-economic status, and racial/ethnic group, and a range of other multifaceted factors, on vaccine access, acceptance and uptake—all of which can be made more complicated by SCDM recommendations.

Reported implementation challenges for vaccines with SCDM recommendations are broad sweeping, impacting providers, patients, vaccine management processes, and reimbursement mechanisms. Further,

while the barriers related to SCDM have the potential to impact patients from all demographic groups, SCDM barriers may be particularly burdensome for the country's most vulnerable, underserved populations, intensifying health disparity gaps and negatively impacting ongoing and concerted efforts to facilitate broad vaccine access and improve health equity overall.

In recent years, there seems to be a trend toward recommending SCDM for new and updated vaccines being made available to patients. While these recommendations are not in and of themselves problematic, there are many challenges and outstanding issues that must be resolved and accounted for if the public health community and key decisionmakers want to ensure equitable and broad awareness, administration and uptake among eligible patient populations. As childhood, adolescent, and adult immunization platforms continue to evolve and expand, it is critical that attention be paid to these barriers and challenges, and that going forward, vaccine stakeholders and policymakers closely and carefully consider the implications of SCDM recommendations on vaccine awareness, access, and uptake.



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