

Letter to: NAIC
From: THE NAIC CONSUMER REPRESENTATIVES
Date: AUGUST 13, 2023

On behalf of the undersigned NAIC Consumer Representatives¹, we offer the attached report examining the implementation of no-cost preventive services coverage offered through the Affordable Care Act (ACA). To improve the health of the nation, the ACA requires most health plans to cover certain preventive services without cost-sharing. Access to such services can improve health equity, prevent avoidable conditions, identify life-threatening conditions early, and link people to care and treatment.

Despite its potential benefits, implementation of the ACA's preventive services has been inconsistent. Consumers and providers are not fully utilizing the services, even though the coverage requirements and cost sharing protections are incredibly popular among consumers who know about them. When consumers take advantage of the covered services, they regularly report being erroneously charged cost-sharing.

The *Braidwood Management, Inc. v. Becerra* lawsuit adds additional confusion and uncertainty to this landscape. As the case works its way through the court system, preventive services requirements remain the law of the land and must be enforced. Moreover, state laws requiring preventive services should be unaffected by the eventual outcome of *Braidwood*.

In light of these developments and our ongoing concern for consumers, we commissioned research to closely examine the ACA's preventive services requirements; how insurers are promoting preventive services; implementation successes and gaps; and the status of enforcement efforts. Our research focused on several preventive services with USPSTF Grade A and Grade B recommendations — smoking cessation, pre-exposure prophylaxis (PrEP) for HIV prevention, colorectal cancer screening, and postpartum depression screening — and assessed key plan documents and processes for complete and accurate information that would enable consumers' full access. Additional information and data was gathered through interviews with state regulators who have conducted related examination or enforcement activities, consumers and consumer advocates, health insurance plan representatives, and health care providers.

Key findings from the research include the following:

- » Plan information describing preventive services varied, with gaps and inconsistencies in how services and coverage were described in consumer-facing brochures and fact sheets;
- » Formularies did not consistently list preventive medications as covered without cost sharing and even formularies that did include a notation for preventive medications were often difficult to navigate; and
- » Plan payer guidance that informs how providers code services as preventive was inconsistently available and rarely provided complete information that providers would need to appropriately code and bill preventive services to ensure they are adjudicated as preventive (without cost sharing) instead of diagnostic.

In short, the ways that insurers organize and expose information to providers and consumers is a meaningful barrier to effective understanding and use of preventive service benefits. While regulators have not historically taken a direct oversight role in how insurers organize information for the public, we believe oversight is necessary to ensure that consumers and providers can practically access and use information they need to understand coverage and billing rules. Given these findings, we make the following recommendations to state regulators:

1. Utilize data calls and market conduct exams to assess compliance and the claims process.

State regulators should analyze claims adjudication processes as part of data calls and market conduct exams. This is the only way to understand whether plans are abiding by coverage and cost-sharing requirements. While it is difficult to discern and apply a best practice for claims adjudication without wading deep into medical billing and coding, regulators can and should develop standards that reduce non-compliant processes.

2. Increase state resources to review and act on claims adjudication data.

Analyzing insurance claims processes and datasets for data calls and market conduct exam activities is complex and increasingly important in consumer protection regulation. Departments of insurance should ensure they have sufficient expertise and capacity in claims adjudication as part of data calls and market conduct exams that involve review of plan medical or utilization management techniques.

3. Ensure continued ACA preventive service coverage and cost-sharing protections through state legislative and regulatory action.

In response to the threat to preventive services access raised by the Braidwood litigation, several states have enshrined the ACA's preventive services coverage and cost-sharing protections in state law. Commissioners should work with plans in their states to ensure continued access to these services by securing voluntary commitments from plans and by monitoring and enforcing transparency and notice provisions for any plan design change. State departments of insurance could also explore updates to state benchmark plans to preserve access to no-cost preventive services.

4. Enforce appeals protections for mis-adjudicated or denied preventive services claims.

Confusing appeals processes often put consumers in the middle of what are essentially disputes between a provider (or lab) and their insurer. Regulators should include analysis of cost-sharing appeals processes in market conduct exams and work with plans to ensure simple and transparent processes to correct mis-adjudicated claims.

5. Ensure that Qualified Health Plan (QHP) certification processes adequately assess formularies and other plan documents for preventive services requirements compliance.

Regulators should tighten review of formulary data submitted during the QHP certification process to ensure that preventive services drugs are easily identifiable on formularies and support work to update the SERFF Prescription Drug template to allow drugs to be listed separately for different cost-sharing arrangements.

6. Hold plans accountable for educating consumers and providers on preventive services requirements, including updated clinical guidelines.

Regulators should encourage plans to conduct outreach and education activities including via plan marketing and benefits description documents and in provider engagement activities. Regulators should also work with plans to ensure that documents describing preventive services protections are posted in an accessible place on a plan's website.

7. Establish uniform billing and coding standards.

Part of regulator engagement with plans must include discussion of uniform billing and coding guidance that can be used across plans. This type of standardization of claims adjudication processes is not novel; CMS has undertaken many standardization efforts in Medicare and Medicare Advantage regulation that offer important lessons and potential guidance for state-regulated insurance products.

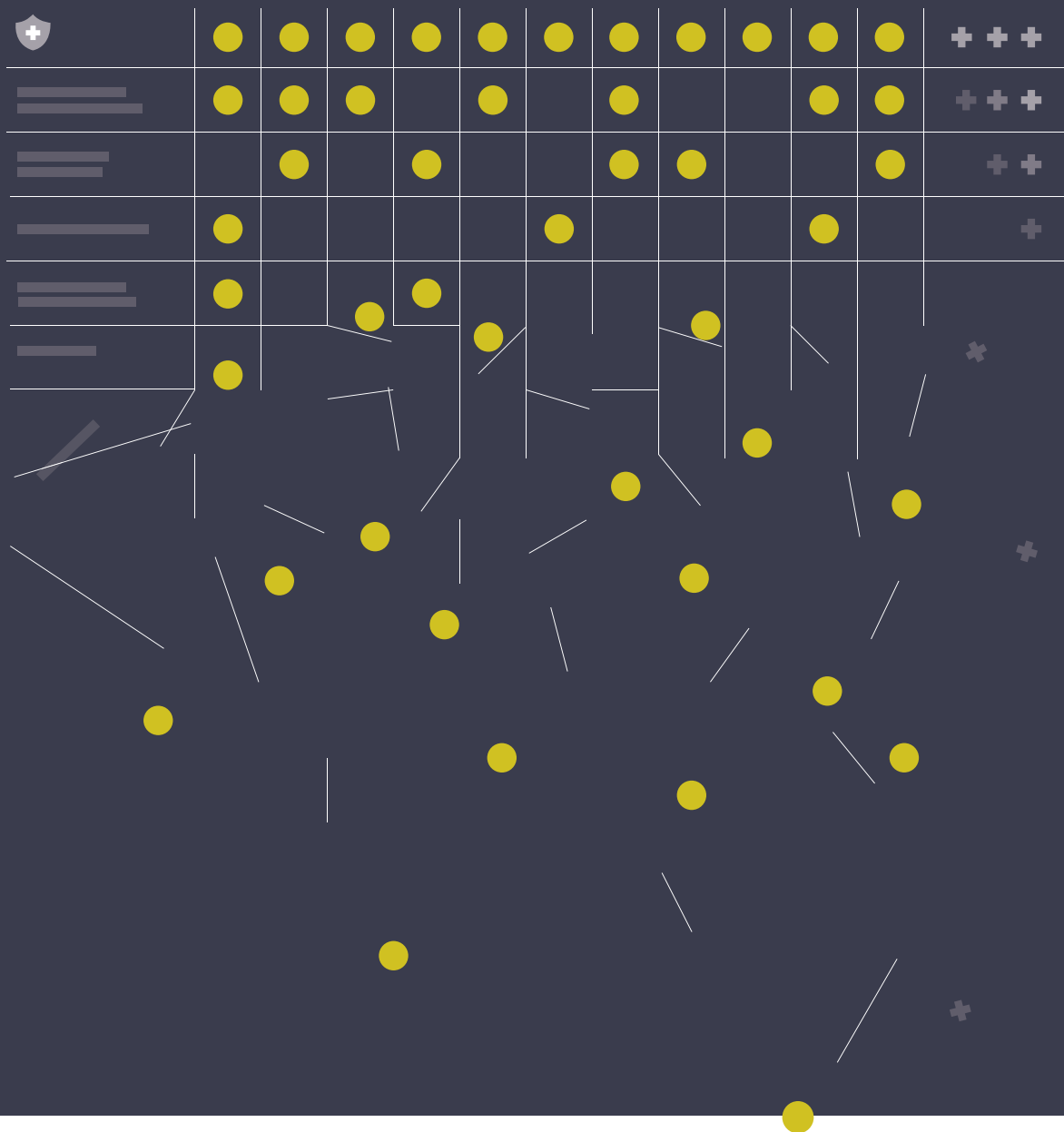
While the findings and recommendations presented above are specific to state regulators, states will be most successful in their efforts with the support of and coordination with the federal government. Federal regulators may consider how they can best enable these recommendations by providing states with helpful resources, policy guidance, and technical assistance.

We are eager to discuss our research, findings, and recommendations with regulators and other stakeholders, and work with all parties to ensure they are realized for the benefit of consumers. Thank you for your attention to this important matter.

Sincerely,

| | | | |
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1. The NAIC works closely with Consumer Representatives to assist state regulators in their primary objective of protecting insurance consumers. The Consumer Representatives do not represent or work for the NAIC, and the views expressed here do not necessarily reflect the views of the NAIC. More information about consumer participation at the NAIC is available at https://content.naic.org/consumer_participation.htm



Preventive Services Coverage and Cost-Sharing Protections Are Inconsistently and Inequitably Implemented

CONSIDERATIONS FOR REGULATORS

AUGUST 2023

ACKNOWLEDGEMENTS

On behalf of the Consumer Representatives to the National Association of Insurance Commissioners (NAIC), Georgians for a Healthy Future contracted with Amy Killelea to research the issues summarized in this report. We are collectively indebted to Amy Killelea for her efforts to prepare this report. The following Consumer Representative Work Group contributed to the report development: Lucy Culp, Yosha Dotson, Eric Ellsworth, Kelly Headerick, Anna Schwamlein Howard, Rachel Klein, Carl Schmid, Wayne Turner, Caitlin Westerson, and Silvia Yee.

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Finally, we also thank the NAIC for supporting opportunities to provide consumer-focused input to insurance regulators on consumer access issues. The NAIC works closely with Consumer Representatives to assist state regulators in their primary objective of protecting insurance consumers. The Consumer Representatives do not represent or work for the NAIC, and the views expressed here do not necessarily reflect the views of the NAIC. More information about consumer participation at the NAIC is available at content.naic.org/consumer_participation.htm.

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Executive Summary

Access to preventive health services averts avoidable health conditions and unnecessary healthcare utilization and provides a bridge to necessary care and treatment. Prevention is also a critical health equity tool that can help address the disproportionate prevalence of certain chronic and communicable diseases across communities that have been marginalized and disenfranchised. The Affordable Care Act (ACA) recognized the importance of preventive services and included a provision that most insurance plans cover a set of high-value, clinically reviewed services without cost sharing.

The following report, commissioned by the Consumer Representatives to the National Association of Insurance Commissioners (NAIC), assessed challenges in access to a subset of ACA preventive services: smoking cessation, pre-exposure prophylaxis (PrEP) for the prevention of HIV, colorectal cancer screening, and postpartum depression screening. The report found that:

- » Plan information describing preventive services varied, with gaps and inconsistencies in how services and coverage were described in consumer-facing brochures and fact sheets;
- » Formularies did not consistently list preventive medications as covered without cost sharing and even formularies that did include a notation for preventive medications were often difficult to navigate; and
- » Plan payer guidance that informs how providers code services as preventive was inconsistently available and rarely provided the full gamut of information providers would need to appropriately code and bill preventive services to ensure they are adjudicated as preventive (without cost sharing) instead of diagnostic.

Based on these findings, the Consumer Representatives call on state insurance regulators to take the following actions to increase monitoring and enforcement of ACA preventive services protections:

- » Utilize data calls and market conduct exams to assess compliance and the claims adjudication processes
- » Increase state resources to review and act on claims adjudication data
- » Ensure continued ACA preventive service coverage and cost-sharing protections through state legislative and regulatory action
- » Enforce appeals protections for mis-adjudicated or denied preventive services claims
- » Ensure that Qualified Health Plan (QHP) certification processes adequately assess formularies and other plan documents for preventive services requirements compliance
- » Hold plans accountable for educating consumers and providers on preventive services requirements, including updated clinical guidelines
- » Establish uniform billing and coding standards

I. Introduction



Ensuring access to preventive services averts avoidable health conditions and unnecessary healthcare utilization and provides a bridge to necessary care and treatment. Focusing on prevention is also a critical health equity tool that can help address the disproportionate prevalence of certain chronic and communicable diseases across communities that have been marginalized and disenfranchised. The Affordable Care Act (ACA) recognized the importance of these services and included a provision that most private insurance plans cover a set of high-value, clinically reviewed services without cost sharing. The Department of Health and Human Services (HHS) estimates that more than 150 million people with private insurance are currently benefiting from the ACA’s preventive service protections.¹ Studies have found that providing access to preventive services without cost sharing has increased utilization and ultimately improved health outcomes.²

However, full implementation of this plan design protection has been challenging. Access to preventive services is impacted by a range of structural and systemic factors, including provider availability and awareness, consumer awareness, and social determinants of health that have an outsized influence on health and wellbeing.³ Full and equitable implementation of coverage and cost-sharing protections for preventive services is also a factor in preventive services access, one that state regulators have a unique role in influencing. As discussed below, a persistent challenge in implementation and compliance has been variable and inconsistent claims adjudication processes across plans, leading to surprise cost-sharing bills and rampant consumer and provider confusion about the circumstances under which services are covered without cost sharing.

The preventive services that the ACA requires plans to cover without cost sharing include screening tests that identify conditions early as well as interventions designed to prevent diseases altogether. Importantly, whether or not the service is “preventive” (and must be provided without cost sharing) or “diagnostic” (which are often still covered, but may have cost sharing) often hinges on whether the individual meets the risk criteria for the intervention and appropriate interval for providing the service. As discussed below, assessing and confirming these factors and accurately categorizing a service as preventive instead of diagnostic can be challenging.

This report uses the preventive services outlined in Figure 1 as a lens to understand the access challenges that persist and the enforcement gaps in these important coverage requirements and protections. These services were chosen because they include prevention interventions with multiple components, sometimes crossing a medical and pharmacy benefit; involve conditions that have a disproportionate impact on marginalized and disenfranchised communities; or involve services with an evolving evidence base and more frequent clinical guidelines updates.

FIGURE 1
Preventive Services Examples Addressed in this Report

| PREVENTIVE SERVICE | USPSTF GRADE |
|--|---|
| Smoking cessation | USPSTF Grade A (last updated 2021) ⁴ |
| PrEP for the prevention of HIV | USPSTF Grade A (last updated 2019) ⁵ |
| Colorectal cancer screening | USPSTF Grade A or B depending on age (last updated 2021) ⁶ |
| Postpartum depression screening | USPSTF Grade B (last updated 2016) ⁷ |

For each of the above services, research included:

1. review of policy analyses and studies on utilization, cost, and health outcomes;
2. analysis of a representative sample of Marketplace plan preventive services and payer guidance documents;
3. informant interviews with patient groups representing constituents impacted by each service or condition;
4. informant interviews with plan and issuer representatives;
5. informant interviews with providers and provider associations, including medical billing and coding subject matter experts;
6. informant interviews with state regulators; and
7. informant interviews with consumers impacted by access challenges.

II. Current Preventive Services Landscape



Preventive services coverage and cost-sharing protections are addressed by federal law, state law, and are also shaped by court decisions.

FIGURE 2 Section 2713 of the ACA

The ACA requires non-grandfathered individual, group, and self-funded plans to cover the following preventive services without cost sharing:

- USPSTF Grade A or B rated services
- Routine vaccines for adults and children recommended by Advisory Committee on Immunization Practices (ACIP) and approved by CDC Director
- Preventive services in guidelines supported by Health Resources and Services Administration (HRSA) via the Bright Futures for Children Program
- Preventive services for women and supported in guidelines by HRSA via the Women's Preventive Services Initiative

Federal-level protections

Section 2713 of the ACA requires non-grandfathered private insurance plans — including individual, fully insured group plans, and self-funded ERISA plans — to cover the clinically reviewed and recommended services described in Figure 2 without cost sharing. The guidelines are typically written by clinical and public health experts without payer guidance (e.g., without translating the clinical recommendations into specific guidance that providers use to submit claims or parameters around appropriate utilization management techniques).

Federal regulations implementing Section 2713 of the ACA allow plans to use “reasonable medical management techniques” to determine the “frequency, method, treatment, or setting” for each service when not specified in the relevant recommendation or guideline.⁸ These medical management techniques include prior authorization for preventive services medication, interval or periodicity requirements for provision of the service, and limitations on the setting in which the service can be provided as preventive.

Compliance with section 2713 has been fraught, with consumers receiving surprise bills for elements of ACA preventive services that should have been covered without cost sharing. These surprise bills have included cost sharing for anesthesia and polyp removal during a colonoscopy and the lab and clinic visits necessary to prescribe PrEP. Because of the challenges in accessing services and non-compliance with cost-sharing protections, patient advocates requested a stronger enforcement role for both state and federal regulators. HHS, the Department of Treasury, and the Department of Labor released a series of sub-regulatory guidance documents to clarify the application of certain preventive services coverage and cost-sharing requirements. These have included frequently asked question (FAQ) documents related to smoking cessation,⁹ colorectal cancer screening,¹⁰ and PrEP.¹¹ These guidance documents provide clarity on the clinically appropriate (or inappropriate) limitations on each service as well as the constellation of services that make up each intervention and that must be covered without cost sharing.

State-level protections

As of June 2023, at least 15 states have enshrined the ACA preventive services protections into state law, requiring individual and/or fully insured group plans to cover the services included in Section 2713 without cost sharing.¹² Other states have passed legislation requiring coverage of individual preventive services — including smoking cessation, PrEP, colorectal cancer screening, and postpartum depression screening — sometimes codifying more specific coverage requirements and affordability protections than federal law.¹³ Importantly, not every state coverage mandate includes the same cost-sharing protections in section 2713 of the ACA.

States have also released guidance — in the form of bulletins and circulars — to state-regulated plans to clarify their obligations under Section 2713 of the ACA and/or parallel state statutes. These guidance documents have included clarification for the circumstances under which plans must cover smoking cessation services¹⁴, PrEP¹⁵, colorectal cancer screening¹⁶, and adult depression screening¹⁷ without cost sharing.

Braidwood Management, Inc. v. Becerra

The ACA preventive services requirements have come under recent litigation threat.¹⁸ In 2020, a religiously affiliated business, Braidwood Management Inc., filed a lawsuit in Texas federal court arguing that the ACA's preventive services requirements, and specifically the requirement to provide PrEP without cost sharing, violated its constitutional and religious freedom rights. In September 2022, Judge Reed O'Connor agreed with the plaintiffs, finding that the ACA's preventive services requirements for coverage of USPSTF Grade A and B services were unconstitutional because, unlike the ACIP and HRSA services, they were not ultimately approved by a federal agency and thus violated the Appointments Clause.¹⁹ Judge O'Connor also found that the requirement for Braidwood to cover PrEP violated the employer's religious freedom rights under the federal Religious Freedom and Restoration Act (RFRA).

In March 2023, following additional briefing on an appropriate remedy, Judge O'Connor issued a nationwide injunction, barring enforcement of the private insurance USPSTF Grade A and B services coverage and cost-sharing requirements issued after March 2010 (when the ACA was passed), which includes PrEP.²⁰ The Administration asked for a temporary stay of the injunction pending appeal, which the Fifth Circuit Court of Appeals granted on May 15, 2023.²¹ Both parties agreed to a joint stipulation in June 2023, which requires plans and employers to continue to provide preventive services without cost sharing during the entirety of the appeals process.²² The federal government agreed not to take any enforcement action

against the plaintiffs during the appeals process. As of June 2023, the Fifth Circuit has yet to issue a ruling in the case. Any ruling by the Fifth Circuit is expected to be appealed to the U.S. Supreme Court.

There are several considerations for state regulators in light of the Braidwood litigation. First, the outcome of the appeal is uncertain and will likely play out over a lengthy process involving both the Fifth Circuit Court of Appeals and the U.S. Supreme Court. In the meantime, the ACA preventive services requirements remain the law of the land and must be enforced by state and federal regulators. Second, as discussed above, a number of states have enshrined preventive services coverage and cost-sharing protections into state law, most of which will remain in place regardless of the Braidwood litigation outcome. While these state-level requirements reach only a segment of the private insurance market and do not include self-funded ERISA plans, they are still an important consumer protection that must be monitored and enforced. And third, the preventive services coverage and cost-sharing protections are incredibly popular among consumers.²³ There is reason to believe that many employers and plans will continue to offer all or some of these benefits with or without a federal or state mandate to do so. It will be important to ensure the plan design is implemented equitably and consistently, without the addition of new cost-sharing or limitations.

III. Health Equity, Cost, and Health Outcome Implications



Access to preventive services can be an important driver of health equity, a cost-saving or cost-effective investment, and a tool to improve individual and public health by either preventing avoidable conditions or identifying conditions early and linking people to care and treatment.²⁴ Though there have been marked improvements in access to preventive services as a result of the ACA's coverage and cost-sharing protections,²⁵ disparities across communities persist, including based on income, race and ethnicity, LGBTQ identification, and disability.²⁶ Figure 3 includes a description of the health equity, cost, and health outcome implications of the coverage and cost-sharing protections for each of the focus preventive services.

FIGURE 3
Health Equity, Cost, and Outcome Implications for Select Preventive Services

| PREVENTIVE SERVICE | HEALTH EQUITY | COST | HEALTH OUTCOME |
|--|---|--|--|
| Smoking Cessation | Tobacco use is concentrated in populations with lower incomes and lower educational levels, and in other specific demographic groups such as in Native American adults, lesbian, gay, bisexual, transgender, and queer (LGBTQ) adults. ²⁷ | Reducing rates of smoking would also reduce health costs related to cancers, respiratory disease, and cardiovascular disease. One study calculated that a 1% reduction of smoking prevalence would result in \$2.5 billion in annual Medicaid savings. ²⁸ | Tobacco cessation interventions double the rate at which people who smoke quit smoking. People who stop smoking reduce their risk of tobacco-related morbidity and mortality and potentially gain up to 10 years of life. ²⁹ |
| PrEP | Over 32,000 people in the U.S. are diagnosed with HIV every year, with Black and African-American and Latino and Hispanic individuals comprising 40 percent and 29 percent of new diagnoses, respectively. ³⁰ In 2021, the CDC found that 78 percent of White Americans recommended for PrEP received a prescription, compared to 21 percent of Latino and Hispanic Americans and just 11 percent of Black and African-Americans. ³¹ | Every person living with HIV requires a lifetime of treatment at an estimated individual cost of about \$501,000, with potential adverse effects that include liver toxicity and insulin resistance. ³² | Only about 30 percent of the 1.1 million people who could benefit from PrEP receive it. PrEP is up to 99 percent effective at preventing acquisition of HIV from sex and at least 74 percent effective at preventing acquisition of HIV from injection drug use. ³³ |
| Colorectal cancer screening | Rates of late colorectal diagnosis and subsequent mortality are higher among rural populations, people with lower education and lower incomes, and people who are Black and African American, Latino and Hispanic, or Native American. ³⁴ | Colorectal cancer causes more than 50,000 premature deaths each year, and accounts for 1.59 % of disability-adjusted life years (DALYs) lost every year in the U.S. to disease. ³⁵ | Colorectal cancer can be prevented through screening. And when colorectal cancer is detected early, it can be treated with surgery, chemotherapy, radiation, and/or immunotherapy, with about 90 percent of people diagnosed able to expect to live quality lives for five years or more. However, only about four out of ten colorectal cancers are detected at an early stage. ³⁶ |
| Postpartum depression screening | About one in seven pregnant and postpartum women nationwide are affected by perinatal mood and anxiety disorders. For low-income women, rates of depressive symptoms are reported to be much higher, between 40 and 60 percent. ³⁷ In addition to income, poor access to education and healthcare, adolescent age, Black and African-American race and recent immigrant status are also associated with higher rates of postpartum depression. ³⁸ | Cost models find that untreated mood and anxiety disorders among pregnant women and new moms cost about \$14.2 billion for births in 2017. ³⁹ | In addition to the health and economic consequences related to mothers experiencing postpartum depression, children of mothers with perinatal mood and anxiety disorders have a higher risk of behavioral and developmental disorders. ⁴⁰ |

IV. Enforcement and Compliance Challenges



To better understand the gaps in preventive services coverage and cost-sharing compliance, we assessed six individual market plans across six jurisdictions.⁴¹ Jurisdictions were chosen for geographic diversity, including different political landscapes, market size, and rural/urban areas. Plans were chosen to ensure a variable sample for analysis. We prioritized plans with a large size of the individual market share in the state and ensured a cross section of plans with national footprints, state/regional plans, and new plan entrants in the last three years. Ultimately, our goal was to identify plans with preventive services designs and policies that are likely not outliers. We assessed three documents for each plan:

- » Consumer-facing preventive services coverage descriptions (i.e., preventive services brochures or fact sheets) on publicly available plan websites
- » 2023 plan formulary
- » Most recent payer guidance for each of the four focus preventive services

See Appendix A for a more thorough description of our plan analysis methodology.

“I was erroneously billed for a postpartum depression screen at my infant’s well-check pediatric visit. I called my issuer about the bill, since I knew the service should have been provided without any cost-sharing on my part. My issuer’s ‘concierge’ then called the pediatric office with me on the phone to connect all of us — but why was I involved in this? I was back at work full-time with a newborn. Why did I have to be involved in figuring this out? The pediatric office said they’d just write off the cost-sharing bill because of the call, but that’s not the right solution either.”

— Erin, large self-funded employer plan

The plan assessment yielded the following findings:

Consumer-facing plan documents often have incomplete information about coverage of preventive services without cost sharing

As Figure 4 shows, even when plan documents reference a particular service, the consumer-facing description is often missing information about what that service includes. Smoking cessation services present a helpful case study of this phenomenon. Though the majority of plans we reviewed listed smoking cessation services as a covered preventive service benefit without cost sharing, not a single plan included both the medication components of the intervention (seven FDA-approved medications for smoking cessation) and the behavioral counseling component that is also a part of the intervention and listed in the USPSTF Grade B recommendation. PrEP coverage presents a similar challenge. Even when plans listed PrEP in a preventive services description, they often failed to include the fact that the intervention includes both the medication and ancillary services, including lab and clinic visits.

FIGURE 4

Consumer-Facing Preventive Services Descriptions

N = six plans

| PREVENTIVE SERVICE | PLAN LISTS THE SERVICE AS COVERED WITHOUT COST SHARING | PLAN COMPREHENSIVELY SPECIFIES THE COMPONENT PARTS OF AN INTERVENTION (e.g., the suite of services that make up the intervention according to clinical guidelines) |
|---------------------------------|--|--|
| Smoking cessation | One no; five yes | Six either missing or major components missing |
| PrEP | Three no; three yes | Five either missing or with major components missing; one comprehensively |
| Colorectal cancer screening | One no; five yes | One missing; four comprehensively or with only some components missing |
| Postpartum depression screening | Four no; two yes | Four either missing or major components missing; two comprehensively |

The plans that did the best job of describing preventive services included easy-to-read charts with each covered service, any demographic or risk requirement for access (e.g., age or gender), and all of the services that make up the intervention and that would be covered without cost sharing.

Formularies were inconsistent in whether and how they displayed preventive services prescription drugs

Three of the four preventive services this report examines — smoking cessation, PrEP, and colorectal cancer screening — have a prescription drug benefit in addition to services covered via the medical benefit. For these three services, we reviewed the plan’s prescription drug formulary as part of our research. *See Figure 5.*

Plans varied in how and whether they accurately displayed preventive services medications in formularies with a clear indication that they are covered without consumer cost sharing. The clearest way to determine whether a drug was covered without cost sharing was to have easy access to a preventive services-specific formulary. These separate formularies were organized by preventive service, making it simple to assess exactly what medications are or are not covered for each service.

Plans that embedded preventive services medications in broader formularies were somewhat more difficult to navigate, especially if the formulary was organized by therapeutic drug class. Even when a drug is correctly listed as having \$0 cost sharing, consumers may not know the drug class of the medications they need, making it difficult to understand what the preventive services protections even are.

FIGURE 5
Preventive Services Formulary Inclusion

| PREVENTIVE SERVICE | PLAN USES SPECIFIC PREVENTIVE SERVICES FORMULARY | PLAN CLEARLY LISTS THE MEDICATION(S) COVERED WITHOUT COST SHARING |
|------------------------------------|---|---|
| Smoking Cessation | Three plans used separate preventive services formularies; three plans included notation about which medications are covered as preventive services without cost sharing in their broader formularies | Four plans list all seven FDA approved medications on either a preventive services specific formulary or broader plan formulary; two plans list six of the seven FDA approved medications for smoking cessation |
| PrEP | | Six plans listed at least one PrEP medication (generic TDF/FTC) without cost sharing; one plan did not list any PrEP medications as available without cost sharing. Of the six plans that listed generic PrEP, one allows access to a brand-name alternative (Descovy) without cost sharing with prior authorization and five exclude all other forms of PrEP (Descovy and Apretude). |
| Colorectal Cancer Screening | | Two plans list multiple bowel prep medications as covered without cost sharing; two plans list one bowel prep medication as covered without cost sharing; and two plans do not list any bowel prep medications as covered without cost sharing. |

Payer guidance documents that inform claims adjudication policies are inconsistent, incomplete, and inaccurate

Payer guidance is the documentation that plans provide to their contracted providers outlining both the clinical criteria for coverage of services and providing instructions for providers to translate a service they deliver into a claim. In the case of preventive services, this includes the appropriate combination of Current Procedural Terminology (CPT) and International Classification of Diseases Tenth Revision (ICD10) diagnosis codes that will be recognized by the payer as required to be covered without cost sharing. Shortly after the ACA's implementation, a modifier code was created for use in identifying preventive services (modifier 33), but this modifier has not been uniformly adopted. Indeed, some payers state specifically in their payer guidance that they will not consider this modifier in determining whether a service is considered preventive for purposes of payment. Without accurate and comprehensive payer guidance, providers are in the dark about how to bill for preventive services and consumers are therefore far more likely to receive an erroneous cost-sharing charge if the claim is billed incorrectly.

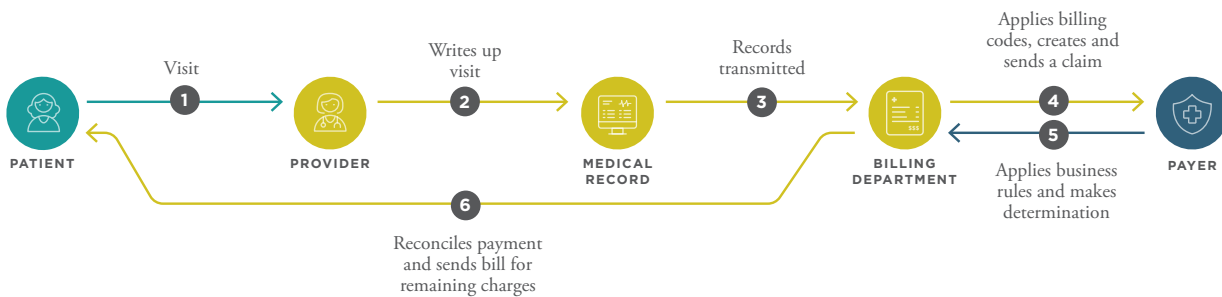
In many ways, payer guidance is the linchpin to plan compliance. It is the document that translates the clinically focused preventive services guidelines into a specific road map as to the circumstances, settings, and services that the plan will cover without cost sharing. *See Figure 6.*

Technology and data systems are another critical part of the system described in Figure 6. The guidance documents that were examined are programmed into insurers' claims adjudication data systems as rules for automated claims review and payment. All submitted claims are run through these rules and checked for required diagnosis and procedure codes, as well as modifier and remark codes that provide additional context about the service. Claims that do not meet the rules programmed into an insurer's data systems are automatically rejected and require labor-intensive reworking to be paid or may be abandoned and never paid at all and/or billed to the patient. Preventive services often require special coding to distinguish their use as a preventive mode of care from other uses of the same procedures in diagnostic or treatment modes.

Despite the outsized importance of payer guidance, our research found that the availability of the payer guidance varied widely across plans and services. Where payer guidance was available, it was incredibly difficult to find, often buried in different parts of plan websites. Even when the payer guidance was located under provider resources sections, the guidance was sometimes combined with clinical criteria documents and sometimes listed as reimbursement or "policy" documents. Moreover, guidance documents were often difficult to sort, often listed as separate PDF document links without a search function. Conversations with plan representatives and medical billing specialists confirmed that locating payer guidance is difficult and that there is no uniform standard for how plans set guidance, or communicate its availability. Guidance can vary greatly from plan to plan and from market segment to market segment. This means that within ACA Marketplace plans, for instance, there could be different payer guidance across Marketplace plans.

In many ways, payer guidance is the linchpin to plan compliance. It is the document that translates the clinically focused preventive services guidelines into a specific road map as to the circumstances, settings, and services that the plan will cover without cost sharing.

FIGURE 6
The Role of Claims Adjudication in \$0 Preventive Services



| 1 | 2 | 3 | 4 | 5 | 6 |
|--|---|--|--|---|--|
| Patient visits provider | Provider writes up visit | Records transmitted to billing department | Billing department applies billing codes, creates and sends claim to Payer | Payer applies business rules and makes determination | Billing department reconciles payment and sends bill to patient for remaining charges |
| Provider administers preventive service to patient | Provider enters notes into Electronic Health Record (EHR) | Medical billing team (sometimes in-house, sometimes external vendor) pulls EHR data and codes each encounter with appropriate procedure and diagnostic codes to mark the whole encounter or a suite of services without cost sharing | Billing team submits claim to payers according to payer guidance* or in the absence of payer guidance “throwing codes against the wall” * Plans sometimes provide payer guidance to help providers know how to code for services, but the existence and content of this guidance varies widely. | Payer either: · approves a “clean” claim as preventative, without cost sharing; · denies it; or · approves it as diagnostic and requires cost sharing from the patient | |

Even where payer guidance documents were found, the content and degree of specificity varied considerably. *See Figure 7.*

Of the four services we researched, colorectal cancer screening has by far the most comprehensive payer guidance available for each of the six plans, perhaps owing to the years of concerted advocacy to ensure that payer practice matched clinical guidelines.⁴³ However, the same type of detail is not available for other preventive services, particularly complex services that include multiple components.

FIGURE 7
Preventive Services Formulary Inclusion

| PREVENTIVE SERVICE | Does the plan's payer guidance clearly specify the circumstances under which the preventive service will be covered without cost sharing? | Does the plan reference up-to-date clinical guidelines as part of medical management standard? | Does the plan include a coding guide for the service? |
|---|--|---|--|
| Smoking Cessation | Two yes; one limited without interval specificity; three payer guidance documents not found | Three no; three payer guidance documents not found | Three yes; three payer guidance documents not found |
| PrEP | Four payer guidance documents include PrEP, but omit at least some labs or clinic visits and/or interval specification; two payer guidance documents not found | Four no; two payer guidance documents not found | One yes; three no; two payer guidance documents not found |
| Colorectal Cancer Screening | Six yes | Six yes | Five yes; one no |
| Post-partum depression screening | Three yes; three payer guidance documents not found | Three no; three payer guidance documents not found | Three yes; three payer guidance documents not found |

While some guidance documents included a comprehensive list of each component of the preventive service, including information about intervals for service provision and populations eligible for the service without cost sharing, others merely referenced the service as preventive without any other information. For instance, smoking cessation services and PrEP each consist of multiple services with specific intervals for providing those services. However, only two of the guidance documents for smoking cessation services and none of the documents for PrEP included details on the appropriate intervals for services.

A common finding across plans is simply the lack of clear information or a discernible standard through reference to clinical guidelines that is able to guide provider billing practices. While colorectal cancer screening payer guidance included up-to-date references to recognized clinical standards across every plan, there were no references to nationally recognized clinical guidelines for the other three services, even where payer guidance documents were available.

Many plans also neglected to include the specific codes (procedure and diagnostic) providers should use to accurately flag a claim as preventive, with colorectal cancer screening guidance far more likely to include this level of detail than the other three services. The variation across plans and across services is seemingly arbitrary. Not only does this variation lead to administrative burden, it also results in disparate and sometimes seemingly arbitrary differences on the circumstances under which services are considered preventive or diagnostic. Providers and consumers we interviewed noted that claims that were mis-adjudicated (for instance flagged as diagnostic instead of preventive by a payer, resulting in consumer cost sharing) were frustrating to appeal and often unresolvable.

While our review of payer guidance found an overall lack of clarity and detail, there was one notable exception where the payer guidance documents we reviewed took a more comprehensive approach. This guidance included not only reference to specific considerations for each preventive service, but also a description of relevant state benefits mandates that also impact coverage and cost-sharing requirements for services. This particular guidance was notable for its comprehensive approach to inclusion of multiple preventive services in one document as well as its inclusion of procedure codes, diagnosis codes, and benefit instructions.

Finally, the payer guidance documents we reviewed were also notable for lack of inclusion of any considerations for provision of preventive services for people with disabilities who may require access to services in different settings or by specialty providers. An in-depth analysis of how preventive services claims for people with disabilities are processed by plans, and whether cost sharing is applied more than for people without disabilities, is outside the scope of this report, but the absence of any mention of considerations for this population is notable and raises questions for future research to examine.

“I have now spent over a year fighting the cost sharing I was charged for the labs I needed to get PrEP. Every path was a dead end, hours on the phone with my insurance plan, conversations with my doctor’s office, multiple complaints to my state insurance department, and my cost-sharing charges are now in collections. It is enough to just say, this is too hard, it’s not worth it to continue to be on PrEP.”

— Anthony, small business Marketplace enrollee in Texas

V. Oversight and Enforcement



Reviewing claims data and/or regulating how claims are processed is a growing state and federal priority.

State Oversight

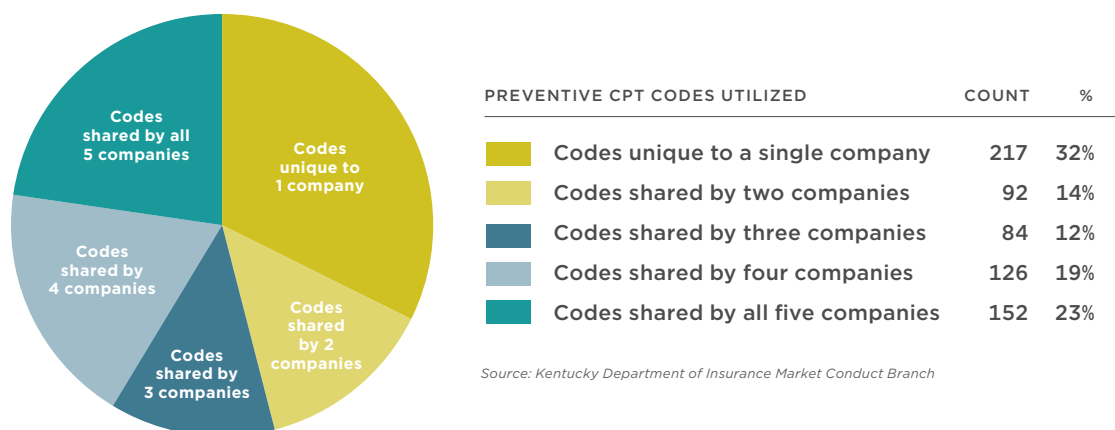
Several states have focused their preventive services enforcement efforts around claims adjudication given its importance in determining what preventive services coverage and cost-sharing protections consumers ultimately receive. The findings from the state market conduct exams, described below, reflect findings similar to those of our plan assessment discussed above.

Kentucky

In 2016, the Kentucky Department of Insurance was awarded a federal grant from CMS to support enforcement of ACA consumer protections.⁴⁴ Kentucky chose to focus its activities on assessing compliance with section 2713 of the ACA and implemented market conduct exams of five insurance carriers in the state. As part of the market conduct exam, insurers were asked to pull claims related to a broad set of 671 CPT codes that the Department determined to be related to preventive services. Of that total, only 23% were used across all five carriers. *See Figure 9.*⁴⁵ The variation means that for each insurer in the state, compliance with the ACA's coverage and cost-sharing protections is dependent on providers being able to decipher the combination of CPT and ICD10 codes that will yield approval from that particular plan. And because there may be limited awareness from consumers with regard to which services should be covered without cost sharing, compliance that is dependent on appeals is likely to miss a large swath of the problem.

When the Department added in ICD10 codes to its analysis, it found the variability to be even greater, with over 92% of the CPT/ICD10 coding combinations unique to an insurer. While one plan in Kentucky recognized 258 ICD10 diagnosis codes to flag a colonoscopy as preventive, the other plans in the state recognized only between two and eight ICD10 codes associated with colonoscopy CPT codes as preventive. The CPT/ICD10 combination variation is particularly troubling as this is often a key part of how claims are determined to be either preventive or diagnostic. The Department has pursued education campaigns with providers, insurers, and patient consumer groups in the state to discuss the market conduct exam findings and identify ways to lessen the variability in coding practices across plans.

FIGURE 9
Kentucky CPT Code Variation for Preventive Services



Oregon

In 2020, the Oregon Division of Financial Regulation issued a data call to better understand plan compliance with the state’s Reproductive Health Equity Act (RHEA), a law that has many parallels and overlaps with section 2713 of the ACA.⁴⁶ The Oregon law includes requirements for preventive services related to reproductive health (e.g., breast and cervical cancer screening and STI screening) to be covered without cost sharing. The Division of Financial Regulation focused its review on a subset of services and found variability in plan compliance, particularly with regard to the requirement for services to be provided without cost sharing.⁴⁷ The Division then decided to conduct market conduct exams for all 12 health insurance plans in the state to audit their compliance with RHEA. A major finding of the exams was that insurers failed to adjudicate claims so that member cost sharing was not applied to the services identified under RHEA. A recommendation from the exams was that insurers review their claims adjudication processes to ensure claims were being accurately flagged as preventive without cost sharing.

“It takes an incredible amount of time and effort to appeal PrEP lab and clinic visit claims that the insurer tags cost sharing to. While some are fixed on appeal, we dip into scarce charitable and public health funds to cover cost sharing for others we can’t get corrected. Without guidance from the plan on how to bill the claim, it’s trial and error across plans.”

— Dr. Joseph Cherabie, infectious disease doctor in at Washington University in Saint Louis, MO

Federal Oversight

Federal agencies have not weighed into claims review in the same ways that state regulators have. While the ACA transparency provisions empower HHS to collect data that would help inform robust enforcement of consumer protections — including “claims payment policies and practices”⁴⁸ — the data collected thus far has been limited.⁴⁹ Data collected has shed some light on overall plan denials and appeals, but very little on whether plans are utilizing arbitrary or non-clinically based claims adjudication processes. CMS may also conduct market conduct examinations for issuers and non-federal government plans to verify compliance with ACA requirements.⁵⁰ Through this process, CMS has the authority to direct the issuer or other responsible entity to forward any documentation CMS considers relevant for purposes of the examination, including claim payment procedures, evidence of claim payment, explanation of benefits, and medical criteria used to make determinations.⁵¹ It is unclear how many (if any) federal market conduct examinations have been used to assess preventive service compliance, but it is certainly an option open to CMS. In general, CMS has not utilized its authority to review plans and respond to violations to the extent it could, leaving a major gap in consumer protections.

Beyond preventive services compliance, understanding and standardizing claims adjudication processes is critical and all but inevitable given the recent move to embed reference to clinical standards and guidelines into federal benefits and non-discrimination requirements⁵² as well as prior authorization standardization.⁵³ There is simply no way to ensure compliance with any standard that is tethered to clinical guidelines — including medical necessity criteria — without assessing how a plan processes claims for these services, the degree payer guidance is comprehensive and available to providers, under what circumstances claims are denied, and under what circumstances claims are paid with or without cost sharing.

VI. Recommendations for Regulators



The following are considerations for regulator action to improve equitable and comprehensive access to preventive services without cost sharing.

1. Utilize data calls and market conduct exams to assess compliance and the claims adjudication processes

State regulators should analyze claims adjudication processes as part of data calls and market conduct exams. This is the only way to understand whether plans are abiding by coverage and cost-sharing requirements. It is also a much more proactive approach than waiting for complaints to trigger regulator action. Complaints may be a particularly inefficient and underinclusive way to address preventive services cost-sharing compliance, as many consumers may not even know they were erroneously charged.

While the incredible variation described in the market conduct exam findings from Kentucky and Oregon above is indicative of a chaotic and arbitrary system of claims adjudication across payers — one that is harming consumers — it is difficult to discern and apply a best practice for claims adjudication without wading deep into medical billing and coding. Still, regulators can and should develop standards that reduce arbitrary and ultimately non-compliant processes. For instance, regulators may require written payer guidance to be produced during market conduct exams and require that payer guidance cite and incorporate clinical guidelines for preventive services to ensure appropriate medical management. Regulators could also do more to ensure that payer guidance documents are readily and uniformly accessible and available to providers.

2. Increase state resources to review and act on claims adjudication data

Analyzing insurance claims processes and datasets for the data calls and market conduct exam activities described above is complex and increasingly important in consumer protection regulation. Departments of insurance should ensure they have sufficient staff (or consultant) expertise and capacity in claims adjudication as part of data calls and market conduct exams that involve review of plans' medical or utilization management techniques. Federal funding could also increase state regulator capacity, as demonstrated by the CMS/CCIIO enforcement funding that Kentucky was awarded to increase monitoring and enforcement activities related to ACA preventive services compliance.

An additional area of capacity regulators should consider developing is oversight of data delivered through an application programming interface (API) (i.e., the way that two computer or software programs talk to each other). Under CMS rules, payers will soon be obligated to provide information on prior authorization requirements through APIs. Monitoring compliance will mean ascertaining both that the APIs are available and functioning properly, and that the information provided through them is accurate and compliant with state and federal rules. This kind of oversight will require personnel with expertise using the APIs to get information as well as assessing the information that is retrieved. We note that payers are obligated to make information available directly to consumers through standardized APIs as well (e.g. the Patient Access API). Soon many consumers are likely to get information on plans, benefits, claims, and other aspects of their health insurance that has never been published in print or even document form. Overseeing compliance with these requirements will likely require personnel with similar expertise.

3. Ensure continued ACA preventive service coverage and cost-sharing protections through state legislative and regulatory action

In response to the threat to preventive services access raised by the *Braidwood* litigation, several states have pursued state legislative efforts to enshrine the ACA preventive services coverage and cost-sharing protections in state law. In some cases, regulators and state Governors sought voluntary commitments from plans to continue to provide preventive services with no cost sharing for consumers. Both Michigan and Washington have called for plans to maintain the preventive services through the entire appeals process for the case.⁵⁴ Securing these commitments continues to be an important action even with the current stay of the injunction in place, as it ensures continued access through the entire appeals process, not just the Fifth Circuit decision. In California, the Commissioner joined with state legislators in calling for state legislative action to ensure continued preventive services consumer protections regardless of the outcome in *Braidwood*.⁵⁵ Commissioners should work with plans in their states to ensure continued access to these services by securing these types of voluntary commitments and by monitoring and enforcing transparency and notice provisions for any plan design change. State Departments of Insurance could also explore updates to state benchmark plans to preserve access to no-cost preventive services in addition to adopting sub-regulatory guidance for preventive services into state regulations and/or bulletins.

4. Enforce appeals protections for mis-adjudicated or denied preventive services claims

The appeals process for erroneous cost-sharing charges in violation of preventive services protections is opaque, for both providers and consumers. Providers have described confusing and frustrating processes, especially in situations where payer guidance is blatantly contrary to clinical guidelines for preventive services.⁵⁶ These confusing appeals processes often put consumers in the middle of what are essentially disputes between a provider (or lab) and the plan. Regulators should include analysis of cost-sharing appeals processes in market conduct exams and work with plans to ensure simple and transparent processes to correct mis-adjudicated claims. Regulators should also ensure there are pathways for providers to submit complaints via state insurance websites in addition to consumers.

5. Ensure that Qualified Health Plan (QHP) certification processes adequately assess formularies and other plan documents for preventive services requirements compliance

Despite the fact that many preventive services have a prescription drug component, we identified gaps in how formularies display \$0 cost sharing medications to their beneficiaries. Regulators should tighten review of formulary data submitted during the QHP certification process to ensure that preventive services drugs are easily identifiable on formularies. Regulators should additionally support work to update the SERFF Prescription Drug template to allow drugs to be listed separately for different cost-sharing arrangements depending on whether they are being used for a preventive purpose (e.g., certain HIV antiretroviral therapies are prescribed for both prevention and treatment of HIV). Regulators should also more closely review how preventive services are displayed in plan materials, including in consumer-facing brochures and payer guidance documents to ensure that services are described accurately and comprehensively.

6. Hold plans accountable for educating consumers and providers on preventive services requirements, including updated clinical guidelines

A major challenge in preventive services uptake is consumer awareness of services and willingness to seek them out and provider awareness of clinical recommendations and willingness and capacity to provide them. The plan analysis described above found marked variability in how preventive services were described in consumer-facing plan documents, with several plans missing information that would enable consumers to understand which preventive services are covered without cost sharing. Similarly, the analysis of payer guidance suggests that providers may not have comprehensive information about the scope of preventive services covered without cost sharing either. Regulators should encourage plans to conduct outreach and education activities in conjunction with broader public health campaigns including via plan marketing and benefits description documents and in provider engagement activities. Regulators should also work with plans to ensure that documents describing preventive services protections are posted in an accessible place on a plan's website.

7. Establish uniform billing and coding standards

Part of regulator engagement with plans must include discussion of uniform billing and coding guidance that can be used across plans. While antitrust laws prevent plans from collaborating on this type of guidance together, there is still utility in brokering conversations about existing guides that may provide best practices for claims adjudication. For instance, the National Alliance of State & Territorial AIDS Directors (NASTAD), an association that represents state, local, and territorial governmental public health programs, received funding from the Centers for Disease Control and Prevention (CDC) to develop a billing and coding guide for PrEP. Other professional societies have similarly taken it upon themselves to develop disease or service specific guides. While the ultimate goal may well be to have coding guides created by federal agencies in conjunction with USPSTF, ACIP, and HRSA recommended services, in the meantime, there may be benefit from identifying commonly used and accepted guides to start to address the variability in plan claims adjudication practices.

This type of standardization of claims adjudication processes is not novel. In fact, CMS has undertaken many standardization efforts in Medicare and Medicare Advantage regulation that offer important lessons for state-regulated insurance products. The National Correct Coding Initiative clarified coding standards for all claims submitted under Traditional Medicare, regardless of which Medicare Administrative Contractor processes the claim and whether the service is covered under a Local Coverage Determination or a National Coverage Determination. CMS also recently introduced regulation requiring Medicare Advantage carriers to follow all National and Local Coverage Determinations, and coverage rules outside of those situations must be “based on current evidence in widely used treatment guidelines or clinical literature.”

VII. Conclusion

Given the importance of access to preventive services to individual health, public health, and health equity, it is critical that regulators engage more proactively in preventive services coverage and cost-sharing protection enforcement in their states. Increasing preventive services access will have an outsized impact on communities that experience higher prevalence of conditions that could be avoided or mitigated through early detection and rapid linkage to care and treatment. The work of regulators must include a deeper understanding and regulation of what are often opaque and arbitrary claims adjudication processes that are standing in the way of meaningful and full implementation of consumer protections.

Appendix

To better understand the gaps in preventive services coverage and cost-sharing compliance, we assessed six individual market plans across six jurisdictions. Jurisdictions were chosen for geographic diversity, including different political landscapes, market size, and rural/urban areas. Plans were chosen to ensure a variable sample for analysis. We prioritized plans with a large size of the Marketplace individual market share in the state and ensured a cross section of plans with national footprints, state/regional plans, and new plan entrants in the last three years. Ultimately, our goal was to identify plans with preventive services designs and policies that are likely not outliers. We assessed three documents for each plan:

- Consumer-facing preventive services descriptions (i.e., preventive services brochures or fact sheets) on publicly available plan websites
- 2023 plan formulary
- Most recent payer guidance for each of the four focus preventive services

For each plan, we assessed the following using the criteria described in the right column.

| Plan Assessment Question | Assessment Criteria |
|--|--|
| Does the plan list the service as covered without cost sharing on a consumer facing preventive service list? | Yes No Unable to find |
| Does the plan specify the component parts of an intervention (e.g., the suite of services that make up the intervention according to clinical guidelines)? | Comprehensively Some parts of the intervention are missing Major parts of the intervention are missing Not at all |
| Does the plan reference up-to-date clinical guidelines as part of medical management standard? | Yes No |
| Does the plan include a coding guide for the service? | Yes No |

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48. 45 CFR § 156.220
49. Kaiser Family Foundation, Claims Denials and Appeals in ACA Marketplace Plans in 2021 (February 2023), available <https://www.kff.org/private-insurance/issue-brief/claims-denials-and-appeals-in-aca-marketplace-plans/>
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51. CMS, CCIO Examinations, Audits and Reviews of Issuers: Issuer Resources, available at https://www.cms.gov/CCIIO/Resources/Forms-Reports-and-Other-Resources/Exams_Audits_Reviews_Issuer_Resources-
52. See, for instance, the Notice of Benefit and Payment Parameters for 2023 Final Rule including reference to clinical guidelines in EHB non-discrimination standards, available at <https://www.cms.gov/newsroom/fact-sheets/hhs-notice-benefit-and-payment-parameters-2023-final-rule-fact-sheet>
53. CMS issued a sweeping proposed rule to streamline prior authorization processes in Medicare Advantage plans, state Medicaid and Children's Health Insurance Programs (CHIP) agencies, Medicaid managed care plans, and Qualified Health Plan (QHP) issuers on the Federally-facilitated Exchanges (FfEs). The proposed rule includes transparency requirements for plans to make their clinical criteria and payer guidance documents easily available to providers, something that is also relevant for preventive services payer guidance. CMS, Press Release: CMS Proposes Rule to Expand Access to Health Information and Improve the Prior Authorization Process, December 6, 2022, available at <https://www.cms.gov/newsroom/press-releases/cms-proposes-rule-expand-access-health-information-and-improve-prior-authorization-process>
54. Michigan Department of Insurance and Financial Services, Gov. Whitmer Secures Commitment from Insurers to Protect Coverage for No-Cost Preventive Healthcare for Michiganders, April 6, 2023, available at <https://www.michigan.gov/difs/news-and-outreach/press-releases/2023/04/06/gov-whitmer-secures-commitments-from-insurers-to-protect-coverage-for-no-cost-preventive-healthcare>; Washington State Office of the Insurance Commissioner, Health Insurers Urged to Continue Covering Preventive Services without Cost Sharing, available at <https://www.insurance.wa.gov/news/health-insurers-urged-continue-covering-preventive-services-without-cost-sharing>
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56. NASTAD PrEP Billing and Coding Guide Advisory Group Meeting, March 2, 2023 (notes on file with authors).
57. The original PrEP Billing and Coding Guide was published in 2016 and is in the process of being updated currently.
58. See, e.g., American Academy of HIV Medicine HIV Testing Coding Guide, available at <https://aahivm.org/wp-content/uploads/2017/02/AAHIVM-CPT-Coding-Guide.pdf>.
59. 42 CFR § 422.101



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