Volume 1, Number 3 May–June 2023

THE JOURNAL OF FEDERAL AGENCY ACTION

Editor's Note: To Your Health
Victoria Prussen Spears

A Patchwork in Need of Permanent Repair: The U.S. Framework for Recommending and Covering Preventive Care
Richard Hughes IV and Kevin Lutes

The Food and Drug Administration Won't Budge on Cannabis and Hemp
Eric P. Berlin, Joanne Caceres, and Amy Rubenstein

The Department of Justice Issues New Guidance on Charging, Pleas, and Sentencing
John J. Delionado, Kevin E. Gaunt, and Martha Saine Condyles

The Securities and Exchange Commission Adopted Long-Awaited Executive Compensation Regulations. What Now?
Michael J. Albano, Audry X. Casusol, and Laura Bagarella

Voluntary Carbon Markets: An Overview of U.S. Regulatory Developments
Deborah North and Laura Daugherty

The Committee on Foreign Investment in the United States Says Chinese Investment in North Dakota Agricultural Land Is Outside Its Jurisdiction
Antonia I. Tzinova, Robert A. Friedman, Marina Veljanovska O'Brien, and Sarah K. Hubner

The Environmental Protection Agency Revises All Appropriate Inquiry Regulations
Bryan Keyt, Erin Brooks, Brittainy Cavender, and John Kindschuh

Export Authorizations Pertaining to the U.S. Government: Current Scope and Historical Perspective
Beth Peters and Ashley E. Roberts

fastcase FULL COURT PRESS

The Journal of Federal Agency Action

Volume 1, No. 3 May–June 2023

171 **Editor's Note: To Your Health**
Victoria Prussen Spears

175 **A Patchwork in Need of Permanent Repair: The U.S. Framework for Recommending and Covering Preventive Care**
Richard Hughes IV and Kevin Lutes

199 **The Food and Drug Administration Won't Budge on Cannabis and Hemp**
Eric P. Berlin, Joanne Caceres, and Amy Rubenstein

205 **The Department of Justice Issues New Guidance on Charging, Pleas, and Sentencing**
John J. Delionado, Kevin E. Gaunt, and Martha Saine Condyles

209 **The Securities and Exchange Commission Adopted Long-Awaited Executive Compensation Regulations. What Now?**
Michael J. Albano, Audry X. Casusol, and Laura Bagarella

219 **Voluntary Carbon Markets: An Overview of U.S. Regulatory Developments**
Deborah North and Laura Daugherty

227 **The Committee on Foreign Investment in the United States Says Chinese Investment in North Dakota Agricultural Land Is Outside Its Jurisdiction**
Antonia I. Tzinova, Robert A. Friedman, Marina Veljanovska O'Brien, and Sarah K. Hubner

235 **The Environmental Protection Agency Revises All Appropriate Inquiry Regulations**
Bryan Keyt, Erin Brooks, Brittainy Cavender, and John Kindschuh

241 **Export Authorizations Pertaining to the U.S. Government: Current Scope and Historical Perspective**
Beth Peters and Ashley E. Roberts

THE JOURNAL OF FEDERAL AGENCY ACTION (ISSN 2834-8796 (print) / ISSN 2834-8818 (online)) at $495.00 annually is published six times per year by Full Court Press, a Fastcase, Inc., imprint.

For customer support, please contact Fastcase, Inc., 729 15th Street, NW, Suite 500, Washington, D.C. 20005, 202.999.4777 (phone), or email customer service at support@fastcase.com.

Publishing Staff
Publisher: Morgan Morrissette Wright
Production Editor: Sharon D. Ray
Cover Art Design: Morgan Morrissette Wright and Sharon D. Ray

This journal's cover includes a photo of Washington D.C.'s Metro Center underground station. The Metro's distinctive coffered and vaulted ceilings were designed by Harry Weese in 1969. They are one of the United States' most iconic examples of the brutalist design style often associated with federal administrative buildings. The photographer is by XH_S on Unsplash, used with permission.

Cite this publication as:

The Journal of Federal Agency Action (Fastcase)

Editorial Office

729 15th Street, NW, Suite 500, Washington, D.C. 20005
https://www.fastcase.com/

POSTMASTER: Send address changes to THE JOURNAL OF FEDERAL AGENCY ACTION, 729 15th Street, NW, Suite 500, Washington, D.C. 20005.

Articles and Submissions

Direct editorial inquiries and send material for publication to:

Steven A. Meyerowitz, Editor-in-Chief, Meyerowitz Communications Inc., 26910 Grand Central Parkway, #18R, Floral Park, NY 11005, smeyerowitz@meyerowitzcommunications.com, 631.291.5541.

Material for publication is welcomed—articles, decisions, or other items of interest to attorneys and law firms, in-house counsel, corporate compliance officers, government agencies and their counsel, senior business executives, and anyone interested in federal agency actions.

QUESTIONS ABOUT THIS PUBLICATION?

For questions about the Editorial Content appearing in these volumes or reprint permission, please contact:

Morgan Morrissette Wright, Publisher, Full Court Press at mwright@fastcase.com or at 202.999.4878

For questions or Sales and Customer Service:

Customer Service
Available 8 a.m.–8 p.m. Eastern Time
866.773.2782 (phone)
support@fastcase.com (email)

Sales
202.999.4777 (phone)
sales@fastcase.com (email)

ISSN 2834-8796 (print)
ISSN 2834-8818 (online)

A Patchwork in Need of Permanent Repair: The U.S. Framework for Recommending and Covering Preventive Care

Richard Hughes IV and Kevin Lutes*

This article reviews the inconsistent structure for recommending and covering clinical preventive interventions in the United States. It describes the various federal agencies and advisory bodies responsible for making these recommendations and their varied criteria, processes, and approaches. It also discusses the uneven market applicability of preventive services coverage requirements and resulting access barriers. Finally, it envisions a new framework for preventive recommendations.

In late 2021, the Food and Drug Administration (FDA) approved a long-acting, injectable (LAI) pre-exposure prophylaxis (PrEP) for at-risk adolescents and adults.[1] Experts heralded this novel intervention as a critical tool to reduce the transmission of HIV. Yet, our nation's fragmented preventive services coverage framework creates hurdles and delays that prevent patients from timely accessing PrEP and other preventive services. A patchwork of bodies recommending first-dollar coverage for preventive services results in unclear recommendations, which are then exacerbated by uneven market applicability and hurdles created by the implementing rules of the Affordable Care Act (ACA). While this collectively affects access to many preventive services, PrEP in particular is an exemplar of the systemic shortcomings we address.

The recent and ongoing litigation[2] in the U.S. District Court for the Northern District of Texas in *Braidwood v. Becerra* (formerly *Kelly v. Becerra*) highlights the structural weakness of the nation's patchwork preventive services recommendation and coverage framework.

Specifically, Judge Reed O'Connor held that the recommendations of the U.S. Preventive Services Task Force (USPSTF or Task Force) for requiring payors to provide first-dollar coverage for PrEP violated the Appointments Clause of the U.S. Constitution because

The Journal of Federal Agency Action / May–June 2023, Vol. 1, No. 3, pp. 175–198.

ISSN 2834-8796 (print) /ISSN ISSN 2834-8818 (online).

the Task Force's members exercise powers akin to officers of the United States yet are not nominated by the president or confirmed by the Senate. While undermining the Task Force's authority could threaten access to preventive health care for millions of Americans, the ruling comes at a time when the Task Force's own insularity and lengthy processes stand in the way of timely access.[3]

Thus, while we are not suggesting our agreement with the court, its ruling underscores a larger structural problem—the Task Force, and other recommending bodies, were designed with a degree of inconsistency that meaningfully affects access to preventive health care. The federal government delegates its responsibility to recommend coverage for preventive services not only through inconsistent appointment processes, but to bodies whose criteria and process for developing recommendations are incongruent. This lack of uniformity creates inconsistencies that undermine access to preventive care and potentially perpetuate health inequities. Moreover, these recommendations are translated inconsistently into coverage policy, resulting in access challenges.

Coverage Fragmentation: The Imperfect ACA Preventive Services Coverage Provision

As part of its larger aim of increasing access to health care coverage and improving the content of said coverage for millions of Americans, Congress included various benefit requirements under the ACA. One of the most prominent requirements is that which requires commercial health insurance plans to provide first-dollar coverage of recommended preventive services, which Congress adopted through Section 2713 of the Public Health Service Act (2713). Via the ACA's Essential Health Benefits (EHB) provision, this requirement also applies to Medicaid expansion populations but does not apply to traditional Medicaid or Medicare.

Despite its popularity,[4] the ACA's preventive services coverage requirement stops short of providing comprehensive assurances of coverage and access. Statutorily, the ACA does not apply 2713 to all markets, leaving an unevenness in market applicability and in the substance of preventive services coverage across private health insurance, Medicaid, and Medicare. Moreover, 2713's implementing rules provide for lengthy implementation periods and substantial payor latitude that may undermine access.

Uneven Market Applicability

Perhaps most glaringly, 2713's coverage requirements do not apply evenly across all sources of health coverage, applying only to commercial health plans and states that expanded Medicaid eligibility under the ACA.[5] This means that Section 2713 does not apply to traditional Medicaid or Medicare.

Instead, under Medicare, preventive services coverage entails a limited and ossified selection of covered services. It exists as its own patchwork of congressionally prescribed screenings and services, listed at length in Section 1861 of the Social Security Act under Part B of Medicare's outpatient medical benefit.[6] This includes coverage for an annual wellness visit, certain vaccines, pelvic and pap smear screenings, prostate cancer screening tests, colon cancer screening tests, cardiovascular screening blood tests, and diabetes screening tests. The Secretary of the Department of Health and Human Services (HHS) has discretion to add additional preventive services listed under Section 1861(ddd). Medicare has created exceptions for some interventions that allow nontraditional beneficiaries to receive first-dollar coverage for certain preventive services, such as colorectal screening beginning at age 45,[7] and HIV screening for individuals age 15 and older, and at-risk populations younger than 15 or older than 65.[8] Adding to the complexity, vaccines not covered under Medicare Part B are covered under the program's prescription drug benefit or Part D.

This approach of statutorily prescribing specific benefits is starkly different from 2713's deference to recommending bodies. Absent the Secretary's proactive use of Section 1861(ddd) authority, it makes for a static approach to covering clinical preventive interventions, one that does not evolve alongside scientific innovation and advancements in preventive modalities.

Under Medicaid, beneficiaries under the age of 21 are assured access to certain preventive services under the Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) benefit.[9] EPSDT includes comprehensive screening and diagnostic services and vaccines among other services. Yet, there is no comparable preventive coverage requirement for adults in Medicaid, meaning that low-income pregnant women in traditional Medicaid, along with low-income individuals in the current 11 states that have not expanded Medicaid coverage, do not have the assurance of receiving preventive care.

2713's Implementing Rules

While the statute itself merely enumerates a list of bodies and specifies that the recommendations of each must be covered without patient cost sharing, 2713's implementing rules at 45 CFR § 147.130 provide the parameters of this coverage. The implementing rules inherently and unnecessarily limit the circumstances in which the requirements apply. For example, the section specifies that first-dollar coverage only applies in situations involving in-network providers. Further, Section 2713 permits payors to employ "reasonable medical management" and delays payor requirements to provide first-dollar coverage. As implemented, these provisions leave otherwise covered preventive services subject to cost-sharing or noncoverage, inhibiting patient access.

Out-of-Network Coverage

Under the implementing rules, payors may impose cost sharing for preventive services delivered by out-of-network providers.[10] But payors are required to provide first-dollar coverage for out-of-network services if their network lacks a provider who can provide the recommended service. This means that a person seeking a vaccine or PrEP for HIV from a provider, perhaps a retail pharmacy, that is out-of-network may encounter cost sharing that may discourage uptake, unless the person can demonstrate the lack of an available in-network provider. This barrier in need of a solution was acknowledged when Congress passed the Coronavirus Aid, Relief, and Economic Security Act or CARES Act, which requires reimbursement parity for out-of-network providers delivering COVID-19 diagnostic testing and forbids cost sharing for the same.[11]

Delayed Implementation of Coverage

Under 2713's implementing rules, payors must provide coverage for recommended services for plan or policy years beginning the year after the one-year anniversary of a new recommendation or guideline.[12] For example, in 2022 the Task Force published its recommendation for screening anxiety in children and adolescents.[13]

As a result, payors are not required to provide first-dollar coverage for this screening until January 2024. Again, during the COVID-19 pandemic, Congress sought to address problematically prolonged implementation under 2713 by requiring expedited payor coverage of COVID-19-related preventive services and vaccines, shortening the above time frame to a mere 15 days following a recommendation.[14]

Reasonable Medical Management

The rules also state that "nothing prevents a plan or issuer from using reasonable medical management techniques to determine the frequency, method, treatment or setting for an item or service" if not otherwise specified in the recommendation or guideline.[15] In doing so, payors are permitted to make their own determination based on relevant evidence and "established medical management techniques" to determine when to cover a recommended service. This means that if a recommendation falls short in its particularity, payors, not providers in their medical judgment, determine the requisite access to recommended preventive services.

The ACA's Reliance on Varied Preventive Services Recommending Bodies

Rather than statutorily prescribing under 2713 those particular preventive services that payors must cover, Congress opted instead to delegate this responsibility to various existing federal advisory committees and agencies by incorporating their recommendations for preventive services into federal insurance law. These advisory bodies (*see* Table 1)—the Task Force, the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC), the Health Resources and Services Administration (HRSA), and the Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC)—all work toward a common goal of enabling access to preventive services, screenings, and immunizations.

The mandate of these bodies greatly expanded with the ACA's enactment, transforming their roles as mere evidenced-based recommenders to that of arbiters of the contents of health insurance

Table 1. Recommending Bodies for Preventive Services

Recommending Entity	Enabling Law	Supporting Agency	Recommended Interventions	Appointments
United States Preventive Services Task Force (USPSTF)	42 U.S.C. § 299b-4(a)(1), *authorizing the Director of AHRQ to convene the USPSTF*	Agency for Healthcare Research and Quality (AHRQ)	Clinical preventive services	Members appointed by the director of AHRQ
Advisory Committee on Immunization Practices (ACIP)	42 U.S.C. §217a(a), *delegating authority to the HHS Secretary to create advisory committees*	Centers for Disease Control and Prevention (CDC)	Vaccines	Members appointed by the HHS Secretary
Health Resources and Services Administration (HRSA) (Bright Futures/ Women's Preventive Services Initiative (WPSI))	47 Fed. Reg. (Aug. 31, 1982), *establishing HRSA*	N/A (federal agency)	Infants, children, youth, and young people/ women's preventive health care services and screening	N/A (federal agency)
Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC)	42 U.S.C. §217a(a), *delegating authority to the HHS Secretary to create advisory committees*; and 42 U.S.C. §300b-10, *requiring the HHS Secretary establish ACHDNC*	HRSA	Newborn screening services listed in Recommended Universal Screening Panel (RUSP)	Members appointed by the HHS Secretary

coverage. However, each was created prior to the ACA and possesses unique histories, make-ups, and organizational purviews that create a confusing and often disjointed recommendation patchwork. This confusion manifests not only clinically for providers aiming to follow the recommendations in practice, but also when determining payor coverage requirements, all of which affects patient access.

Thus, by enacting Section 2713, Congress made a well-meaning attempt to create a comprehensive preventive care services framework. But its reliance in doing so on the recommending bodies foisted a responsibility on them for which they were not designed. The bodies were first empowered prior to the ACA through varied statutes and appointment processes. The ACA did not alter this variation.

As they have adapted to their new responsibilities, the recommending bodies' lengthy and disjointed review processes have not evolved to accommodate the bodies' roles as arbiters of coverage. Their differing recommendation methodologies and outputs result in coverage policies that are confusing at best and undermine patient access at worst. These structural inconsistencies and fragmentations do not exist in a vacuum but interact to raise unique barriers to patient access, as illustrated here through the examples of HIV prevention, contraceptives, and vaccines. Moreover, the potential for future overlapping jurisdictions in certain disease areas such as HIV and hepatitis raises the specter of infinite confusion over clinically appropriate care.

U.S. Preventive Services Task Force

The first named body under 2713, the Task Force, is charged with recommending evidence-based preventive services offered in the primary care setting such as screenings, counseling services, and preventive medications.[16] Formed in 1984, the Task Force sought to act as a "leading independent panel of non-Federal Experts in prevention and evidence-based medicine."[17] Now, a committee within the Agency for Healthcare Research and Quality (AHRQ), the Task Force assigned recommendations that require first-dollar coverage for preventive services that receive a grade of A or B. Structurally, the USPSTF is comprised of 16 volunteer members appointed by the director of the AHRQ, who specialize in primary care, prevention, and evidence-based medicine.

Advisory Committee on Immunization Practices

While the USPSTF recommendations cover clinical services and previously recommended vaccines, in 1996 it began deferring to the ACIP, which is charged with recommending immunizations.[18] Established in 1964 by the Surgeon General of the U.S. Public Health Service, ACIP was charged with advising the Surgeon General on "the most effective application in public health practice of specific preventive agents which may be applied for communicable disease control."[19] Today, ACIP considers clinical, economic, and humanistic evidence to arrive at one of three recommending conclusions: (1) ACIP does not recommend the intervention as used within FDA-licensed indications; (2) ACIP recommends the intervention for individuals based on shared clinical decision-making; or (3) ACIP recommends the intervention.[20]

However, ACIPS's structure and recommendation framework differs significantly from the USPSTF. Structurally, ACIP is made up of 20 voting members selected by the CDC director from authority delegated by the HHS Secretary.[21] Additionally, ex-officio members from HHS, FDA, CDC, National Institutes of Health (NIH), Indian Health Service (IHS), and Office of Infectious Disease and HIV/AIDS Policy, and liaison representatives from various specialty societies, public health organizations, and trade associations advise the committee as it develops recommendations. The full committee votes on its recommendations on the advice of working groups that have reviewed evidence. The CDC director must then approve the recommendations prior to their official publication in the CDC's Morbidity and Mortality Weekly Reports (MMWR).

Health Resources and Services Administration

Established in 1980 as an agency within the HHS, HRSA ensures access to health care services for uninsured, isolated, or medically vulnerable.[22] Unique among the recommending bodies as an agency rather than advisory committee, HRSA was tapped under 2713 to recommend preventive care and screenings for infants, children, adolescents, and women.

Unlike the Task Force and ACIP, HRSA delegates many responsibilities for the development of its recommendations to various medical specialty societies.[23] Through the Bright Futures Program, the American Academy of Pediatrics recommends preventive

services and screenings that focus on infants, children, youth, and young people for coverage without cost sharing.[24]

Upon initial implementation of 2713, HRSA sought the advice of the former Institute of Medicine. In turn, HRSA adopted guidelines recommending coverage of all FDA-approved "contraceptive methods, sterilization procedures, and patient education and counseling for all [persons] with reproductive capacity."[25] Specifically, it requires that payors cover at least one contraceptive product per FDA-designated category. This is colloquially known as the "contraceptive mandate."

The American College of Obstetricians and Gynecologists (ACOG) recommends comprehensive preventive services to HRSA through the Women's Preventive Services Initiative (WPSI).[26] Since 2016, HRSA has contracted with WPSI to make clinical recommendations for updated guidelines.[27]

Advisory Committee on Heritable Disorders in Newborns and Children

Perhaps the most obscure of the bodies referenced by 2713, the ACHDNC, is an advisory committee within HRSA.[28] Established in 2003 by HRSA, the ACHDNC was created to advise the HHS Secretary about newborn and childhood screening.[29] It recommends screenings to detect disorders in newborns, which comprise its Recommended Uniform Screening Panel.[30] ACHDNC is composed of Organizational Representatives who have a broad interest in newborn screening appointed by the Secretary of HHS.[31]

The Bodies' Unique Origins Create Constitutional Issues for 2713

The pre-existing variability among the bodies, when overlayed with 2713-heightened responsibilities, has left the recommending bodies vulnerable to legal challenges. The plaintiffs in *Braidwood v. Becerra*, employers who object on moral grounds to certain coverage requirements, including HIV prevention, challenged the constitutionality of the bodies' roles. The plaintiffs posited that members of the Task Force, ACIP, and HRSA, as empowered by Section 2713, are officers of the United States and their recommendations violate

the Appointments Clause of the U.S. Constitution because they lack presidential nomination and Senate approval.

The court upheld ACIP and HRSA's roles as constitutional because their recommendations are ratified by officers of the United States, the director of the CDC, and the HHS Assistant Secretary, respectively. But in contrast, the court found the Task Force's insular appointments and recommendation process unconstitutional.

The court ruled that Task Force's recommendation framework violated the Appointments Clause because the Secretary of HHS lacks oversight of the recommending body and that its members exercise powers of Officers of the United States without being nominated by the president and approved by the Senate. Under the Task Force's appointment process, the unconfirmed AHRQ Director appoints members to the body, rather than the HHS Secretary. The court reasoned the HHS Secretary lacks authority over the Task Force's coverage recommendations, citing unique insulating language in its authorizing statute: "[members] shall be independent and, to the extent practicable, not subject to political pressure."[32] Thus, the Task Force members were found to exercise powers of an officer of the United States because they occupy a "continuing position established by law … and exercise significant authority pursuant to the laws of the United States. . . ."[33]

Although the ruling spared ACIP and HRSA, the plaintiffs requested relief that would specifically invalidate Task Force recommendations made since 2010. The district court is expected to rule any moment, leaving the future of the Task Force and access to preventive care for millions of Americans in jeopardy.[34]

Inconsistent Recommendation Methodologies and Evidentiary Criteria

Each body has been left to develop its own recommendation methodologies using varied evidentiary criteria, rendering inconsistent recommendations. Without consistent recommendation methodologies, the recommendations issued by the bodies could result in unequal coverage and access for recommended items and services.

The Task Force is the only body for which Congress has specified the criteria it is to evaluate, requiring that it "shall review the scientific evidence related to the effectiveness, appropriateness, and

cost-effectiveness of clinical preventive services for the purpose of developing recommendations. . . ."[35] The Task Force assigns its letter grades based on "the quality and strength of the available evidence about the potential benefits and harms of the preventive service, as well as the size of the potential benefits and harms."[36]

When crafting recommendations, ACIP assesses 11 factors that consider the disease epidemiology and burden of the disease, vaccine safety, vaccine efficacy and effectiveness, economic analyses, feasibility of a recommendation in clinical practice, and patient acceptability.[37]

Within the HRSA framework, the WPSI bases its recommendations on evidence of both benefits and harms of an intervention or service and an assessment of the balance between them,[38] while the Bright Futures' recommendations create clinical guidelines that are age-specific and help increase the quality of primary and preventive care.[39]

Lastly, the ACHDNC recommends newborn screenings by assessing evidence based on the net benefit to the newborn and the feasibility and readiness of state programs to expand screening for the condition.[40]

In addition to using differing recommendation methodologies, the recommending bodies assess different forms of evidence, which may include direct evidence, such as clinical studies, indirect evidence, and economic analyses. When assessing preventive services, the Task Force reviews data of varying quality. Meta analyses and randomized controlled trials provide the Task Force with reliable data. Randomly controlled trials with morbidity or mortality outcomes provide the best insight to the net benefit of a preventive service but are often unavailable or outdated.[41] For example, radiologists and other clinical practitioners criticized the Task Force's 2009 grade C recommendation for screening mammography for women, aged 40 to 49, claiming the Task Force prioritized outdated studies that overemphasized harm.[42] Increasingly, the Task Force has begun to rely on indirect evidence, rather than randomized, controlled trials.[43] In doing so, it assesses a chain of evidence that connects the target population to the ultimate health outcome through a series of linked questions.[44] These include studies of intermediate outcomes or surrogate measures.[45]

Despite the statutory mandate to do so, the Task Force does not evaluate cost and maintains that these considerations are excluded to maintain a clear focus on clinical effectiveness and

avoid misperception that the Task Force's purpose is to ration care.[46] The Task Force's claims for clinical integrity belie a political concern that the public would accuse the Task Force of withholding services because of costs.[47] Yet, critics accuse the task force of lowering standards to facilitate screening recommendations.[48] In contrast to the Task Force, ACIP does consider cost effectiveness in the absence of any statutory requirement to do so.

Under HRSA, the WPSI and Bright Futures approach evidence evaluation much like the Task Force and the ACIP. The WPSI evaluates effectiveness of a preventive service using studies applicable to the primary care setting, which include randomized controlled trials, large prospective cohort studies, diagnostic accuracy studies, and "systematic reviews that enroll women and provide relevant data."[49] Much like the Task Force, the WPSI's methodology permits the use of indirect evidence, noting that "[f]indings related to specific populations are included when available." Further, The WPSI uses the same predefined criteria developed by the Task Force to assess bias risk in data. But like the ACIP, Bright Futures' methodology statement offers little information on how the body defines the scope of pediatric prevention, prioritizes services for review, or evaluates individual services. Instead, Bright Futures cites to professional guidelines and clinical studies as primary sources of evidence and lists effectiveness as a core criterion.[50]

Lastly, the ACHDNC reviews unique evidence in making its recommendations. Instead of evaluating randomized clinical trials or indirect evidence, the ACHDNC reviews pilot studies, which are defined as systematic investigations or public health activities that are designed to evaluate the efficacy and safety of incorporating a new test or condition on a population-based level into a state newborn screening program.[51]

Differing Recommendation Systems Confuse Payors, Providers, and Patients

When taken into context, the numerous forms of evidence and the underlying questions upon which the evidence is assessed obfuscates the recommendations' meaning. Without a clear meaning, patients, providers, and payors are ill-equipped to effectuate first-dollar coverage for covered services. Further compounding these challenges, each recommending body articulates its recommendations in varied formats.

The Task Force recommends clinical preventive services by assessing an intervention's benefit and certainty of the benefit's occurrence. It then assigns a value descending from A to D to assess benefit value and certainty of occurrence, or "I" when there is insufficient evidence to assess the service adequately.[52] However, Section 2713 only requires coverage without cost sharing for services that receive an A (a high certainty that the net benefit is substantial) or a B (high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial) rating.

The ACIP makes recommendations for routine immunization in certain age- or risk-based cohorts, but also recommends immunization based on "Shared Clinical Decision-making."[53] Meanwhile, HRSA merely lists recommended services, while relying on the FDA for the development of specific contraceptive categories.[54]

These varied approaches to recommendations can result in confusion among payors, providers, and patients alike, resulting in denied coverage and access. For example, because a patient's decision to receive preventive services, such as vaccines, is strongly influenced by the patient's provider's recommendation, providers must be able to articulate the body's recommendation,[55] and explain its application to the individual patient.[56] But ACIP's framework leaves many providers ill-equipped to communicate recommendations to patients as they cannot interpret shared clinical decision-making recommendations.[57] Likewise, payor coverage of these recommendations has been inconsistent despite a requirement under 2713's implementing rules that they provider coverage of all immunizations on ACIP's schedule.[58] In February 2020, the CDC issued Frequently Asked Questions seeking to clarify the differences in ACIP recommendations and clarifying that shared clinical decision-making recommendations are entitled to first-dollar coverage under 2713.[59]

Likewise, HRSA's tethering of its recommendations to the FDA-created "Birth Control Guide" has created confusion for contraceptive coverage. Under the current guidelines, HRSA requires plans to automatically cover only one contraceptive product for each of the 17 specific FDA-determined categories.[60] This means that payors may use "reasonable medical techniques" so long as at least one product per category receives first-dollar coverage.[61] In turn, patients are subjected to a fail-first methodology, requiring patients to use the covered product before they may receive the

medically appropriate product. This places the burden on patients and providers to understand and exercise their right to engage with their plan's administrative appeals process and undercuts a provider's ability to recommend contraceptives that are medically appropriate for an individual patient.[62]

In seeking to clarify contraceptive coverage requirements last year, the Biden administration disavowed the FDA chart, characterizing it as an educational rather than binding policy document. It suggested that payors are required to provide first dollar coverage of new forms of contraceptives despite the lack of a distinct category for those products.[63] No other recommending body adopted the one-per-category approach, though CMS's (Centers for Medicare & Medicaid Services) 2021 Frequently Asked Questions interpreting coverage requirements under the Task Force's recommendation of PrEP for HIV adopted a similar approach, permitting payors to apply utilization management techniques.[64] Meanwhile, the ACIP recommends a host of vaccines in categories comprised of multiple products, reflecting the ability of providers to choose specific vaccine products to offer patients without the concern that a particular product will not be covered. Each of the recommending bodies has this authority under 2713's implementing rules to specify which items and services must be covered, and each could articulate its recommendations to foster access to multiple products.

Perhaps the most egregious shortcomings of this variety reside with the Task Force. As described above, the Task Force was unfortunately nonspecific as to the method, treatment, or setting of delivery when it issued its initial grade A recommendation for PrEP for HIV in 2019.[65] Subsequently, CMS clarified that issuers may cover generic PrEP without cost sharing and may impose cost sharing on an equivalent branded version that falls outside of the payor's formulary. The CMS guidance requires payors to provide first-dollar coverage for brand or nonpreferred particular prep services that a clinical provider has determined to be medically appropriate to an individuals health. Yet this does not entirely resolve barriers to patient access because it requires both the patient and the provider to be aware of this requirement, and have the resources to engage with the payor's mechanism to waive the otherwise applicable cost-sharing. This risks increased adverse events where the payor's preferred product is medically inappropriate. In turn, this may risk nonadherence, increased probability of HIV transmission, and poorer health outcomes.

In what would outwardly appear to facilitate greater access, the Task Force has added insult to injury by reopening its recommendation process to evaluate LAI PrEP. As discussed above, the first LAI PrEP was approved in 2021. Rather than pronouncing that its existing recommendation encompasses new forms of PrEP, the Task Force has proceeded as if it were required to reevaluate its recommendation.[66] As recently suggested, the Task Force could have simply interpreted its existing recommendations to encompass LAI PrEP so that coverage could take effect.[67] It could have facilitated this interpretation by incorporating the CDC's comprehensive PrEP guidelines, which describe all available PrEP products in detail.[68] Moreover, the Task Force is required by law to consider "clinical preventive best practice recommendations" by the CDC if it needed any further support for such a decision.[69]

Disjointed, Lengthy Review Processes Delay Access to Coverage

Lengthy review processes and a lack of coordination between the recommending bodies and other regulators may compromise access to the very services the recommending bodies are intended to guarantee. Currently, each body maintains its own recommendation methodology and intake practices, placing each new intervention, no matter how innovative or promising for public health, on a highly individualized, unpredictable time line. For example, the Task Force may spend up to five years reviewing new products and services before it makes a recommendation, relying on a multistep process—review topic nominations, develop a draft research plan, review public comments and finalize the research plan, review evidence and develop a draft recommendation, review public comments again and finalize recommendations. Moreover, it uses a four-point prioritization system to determine which services to assess.[70]

LAI PrEP is the most recent subject of the Task Force's delay. By reopening its lengthy multistep process to consider LAI PrEP, the Task Force has restarted the proverbial clock. The Task Force issued its first recommendation for PrEP services seven years after its FDA approval. Now, its decision to restart its recommendation process in lieu of applying its recommendation to new modalities further delays coverage and access. This is, of course, exacerbated

by 2713's implementing rules, allowing payors to delay first-dollar coverage until the next plan year beginning after the one-year anniversary of a new recommendation. On its current path, assuming the Task Force issues a favorable recommendation this year, first-dollar coverage for LAI PrEP is unlikely before January 2025.

Likewise, HRSA's decision to rely on the FDA's chart has delayed coverage for new contraceptives, as the FDA infrequently updates its guide to reflect new, innovative modalities. In this reliance, HRSA has in essence neutered its own flexibility to adopt novel contraceptives.

Under the 21st Century Cures Act, Congress sought to speed vaccine access, create greater certainty, and foster innovation by requiring the ACIP to establish predictable review time lines, including reviewing newly approved vaccines at its next regularly scheduled meeting.[71] As described above, in further recognition and acknowledgment of the lengthy time lines and added delay under 2713's implementing rules, Congress enacted a provision under the CARES Act to require rapid coverage of a qualifying coronavirus vaccine within 15 days of receiving an A or B rating from the Task Force or a recommendation from ACIP.[72] Congress has not enacted similar requirements for the other recommending bodies. Congressional intervention is less than ideal for several reasons. With respect to the Cures provision, it merely required ACIP to vote or provide a report, but has not meaningfully sped its time lines. ACIP did act with due speed with respect to COVID-19. However, Congress's intervention to speed coverage time lines is an indicator that the administrative apparatus could take its own steps to speed both recommendation time lines and payor coverage implementing under 2713's implementing rules.

A Future Clash of Jurisdictions?

Future innovations will not only encounter the above-described barriers, but many will straddle the boundaries of the recommending bodies in such a way that none has clear responsibility or purview. The USPSTF has recommended Hepatitis B screening for adolescents and adults at increased risk with a B grade since 2020.[73] In recommending universal Hepatitis B vaccination in 2022, the ACIP eliminated its recommendation for pre-vaccination testing.[74] This is an instance where a lack of coordination

in recommendations could cause clinical confusion as to which patients should be screened and vaccinated.

The HIV vaccine is perhaps the most awaited public health intervention of our lifetime, yet how will it be recommended? While immunizations ordinarily fall within the purview of ACIP, PrEP has been the responsibility of the Task Force. If the Task Force undertakes the responsibility of making a recommendation, delay would be inevitable. If the ACIP does so, the recommendations for vaccines vis-à-vis PrEP could be incongruent, create confusion in clinical practice, and undermine efforts to end the HIV epidemic.[75] The CDC and ACIP have shown a degree of flexibility in that ACIP's charter was revised to reflect its responsibility to recommend the "use of specific antibody products for prevention of infectious diseases."[76] Antibodies played an important role in protecting the immunocompromised from COVID-19 infection, new monoclonal antibodies provide hope for protection of infants against respiratory syncytial virus (RSV), and several HIV antibody candidates are in development. Therefore, the ability of recommending bodies to adapt along with innovation will become critical to realizing its promises.

Envisioning a New Framework for Preventive Services

Braidwood v. Becerra existentially threatens Section 2713's framework. The urgency it creates should be harnessed to meaningfully reform and improve our nation's approach to recommending and paying for preventive health care. Any such reform should bolster the underlying authority of the recommending bodies to gird against constitutionally problematic exercises of authority. It should also eliminate the structural inconsistencies described herein, smooth implementation hurdles and extend the coverage guarantees of 2713 universally, to all populations regardless of source of health coverage.

First, Congress or the Biden administration could establish a new coordinating body within HHS. This could build upon the existing framework and carry out a charge to align processes, criteria and recommendation approaches across them. Curiously, the Community Preventive Services Task Force (CPSTF) has this obviously unfulfilled obligation under current federal law.[77] Indeed,

it is required to "take appropriate steps to coordinate its work with the U.S. Preventive Services Task Force and the Advisory Committee on Immunization Practices, including the examination of how each task force's recommendations interact at the nexus of clinic and community."[78] The duties Congress outlined for the CPSTF include "improved integration with Federal Government health objectives and . . . the enhanced dissemination of recommendations." Conceivably, this provides the CDC director, who is tasked with convening the CPSTF, with the necessary powers to take meaningful steps toward alignment and coordination. The CDC is currently undergoing a process of reorganization to address "structural and systemic operational challenges."[79] It should count the above-described challenges among those for which it adapts. Moreover, the creation or enlistment of a coordinating body would increase political accountability, perhaps mitigating constitutional challenges of the variety raised in *Braidwood v. Becerra*.

An alternative, though more extreme, option would be to dissolve the bodies and reconstitute them as a new, unified preventive services body charged with providing all recommendations for preventive services and screenings.

At a minimum, the existing bodies should be encouraged to coordinate among one another, to strive for consistency, and to clarify their own recommendations in a manner that facilitates proper coverage and access. The ACA greatly increased the responsibility of these bodies. None are equipped to regulate insurance, but the resources of the federal government should be dedicated to assisting each in meaningfully clarifying and implementing their recommendations. The ACIP's issuance of FAQs to clarify shared clinical decision-making recommendations is an exemplar.

The stakes of providing or denying timely access to preventive care are too high for a "head in the sand" posture. This is why HRSA should decouple the contraceptive mandate from the FDA and the Task Force should operate not as if it is atop an "ivory tower" but as a facilitator of access to innovations such as LAI PrEP that hold the promise of reducing the transmission of HIV.

While we would not suggest speed at the cost of developing appropriately evidence-based recommendations, there is ample opportunity to improve the timeliness of recommendations. A bit of pandemic urgency would go a long way. Congress could act, as it did under the Cures Act, to require the Task Force and other bodies to consider recommendations in a more expedient manner. However,

the executive branch could take steps on its own to establish clear time frames for issuing recommendations following FDA approval and to eliminate the disjointed review processes that delay patient access to potentially life-saving preventive services.

Moreover, providing the enjoyment of maximum marketability during a regulatory exclusivity period fosters further innovation and competition in research and development. In turn, this evermore increases our opportunities as a society to intervene to protect population health.

Finally, Congress and the administration could further the promise of prevention by applying 2713 to other health coverage segments, including Medicare and traditional Medicaid. To extend the benefits of comprehensive preventive coverage to all Americans would pay dividends in Medicare savings. Moreover, it would further progress toward a more equitable health care system and more equitable public health outcomes.

Notes

* Richard Hughes IV is a partner at Epstein Becker Green and a Professorial Lecturer in Law at The George Washington University. He provides counsel, with a particular emphasis on vaccines, prevention, and early intervention, to biopharmaceutical and device companies and a variety of health care clients. Kevin Lutes is a Charles F.C. Ruff Fellow at the Office of the Attorney General for the District of Columbia. The authors wish to extend their appreciation to Helaine I. Fingold (a member of the Board of Editors of *The Journal of Federal Agency Action*), William Walters, Nija Chappel, Alessandra Fix, and Sofia Toso for their input and support. The authors may be contacted at rhhughes@ebglaw.com and kvnlutes@gmail.com, respectively.

1. U.S. Food & Drug Administration, FDA Approves First Injectable Treatment for HIV Pre-Exposure Prevention: Drug Given Every Two Months Rather Than Daily Pill Is Important Tool in Effort to End the HIV Epidemic (Dec. 20, 2021), https://www.fda.gov/news-events/press-announcements/fda-approves-first-injectable-treatment-hiv-pre-exposure-prevention.

2. Braidwood Mgmt. Inc. et al. v. Xavier Becerra et al., No. 4:20-cv-00283-O, Mem. and Points of Authority (N.D. T.X. Sept. 7, 2022), https://www.courthousenews.com/wp-content/uploads/2022/09/braidwood-becerra-ruling-usdc-texas.pdf.

3. Richard Hughes IV, Why Are We Delaying Coverage of New HIV Prevention?, Health Affairs Forefront (Jan. 26, 2023).

4. Ashley Kirzinger et al., U.S. Public Opinion on Healthcare Reform, 2017, JAMA 317(15) (2017), 1516, https://jamanetwork.com/journals/jama/article-abstract/2614802.

5. Kaiser Family Foundation, Status of State Medicaid Expansion Decisions: Interactive Map (Nov. 9, 2022), https://www.kff.org/medicaid/issue-brief/status-of-state-medicaid-expansion-decisions-interactive-map/.

6. Codified at 42 U.S.C. § 1395x.

7. CMS, Medicare Physician Fee Schedule, Final Rule (Nov. 18, 2022), pp. 1027-49, re: coverage of colorectal cancer screening starting at age 45.

8. Medicare.gov, HIV Screenings, https://www.medicare.gov/coverage/hiv-screenings.

9. Medicaid.gov, Early and Periodic Screening, Diagnostic, and Treatment, https://www.medicaid.gov/medicaid/benefits/early-and-periodic-screening-diagnostic-and-treatment/index.html.

10. 45 CFR § 147.130(3) (2020).

11. Employee Benefits Security Administration, FAQs About Families First Coronavirus Response Act and Coronavirus Aid, Relief, and Economic Security Act Implementation Part 52 (Feb. 4, 2022), https://www.dol.gov/agencies/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-52.

12. 45 C.F.R. § 147.130(b) (2011).

13. United States Preventive Services Task Force, Final Recommendation Statement: Anxiety in Children and Adolescents: Screening (Oct. 11, 2022), https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/screening-anxiety-children-adolescents.

14. Coronavirus Aid, Relief, and Economic Security (CARES) Act, Pub. L. No. 116-136, § 4203 (2020).

15. 45 C.F.R. § 147.130(a)(4) (2011).

16. United States Preventive Services Task Force, USPSTF and Cost Considerations, https://www.uspreventiveservicestaskforce.org/uspstf/about-uspstf/task-force-resources/uspstf-and-cost-considerations.

17. United States Preventive Services Task Force, Procedure Manual Section 1: Overview of U.S. Preventive Services Task Force Structure and Processes, https://www.uspreventiveservicestaskforce.org/uspstf/about-uspstf/methods-and-processes/procedure-manual/procedure-manual-section-1.

18. United States Preventive Services Task Force, Immunizations for Adults, https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/immunizations-for-adults (last visited Jan. 25, 2023).

19. Centers for Disease Control and Prevention, History and Evolution of the Advisory Committee on Immunization Practices—United States, 1964-2014, https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6342a5.htm.

20. Centers for Disease Control and Prevention, ACIP Evidence to Recommendations Framework, https://www.cdc.gov/vaccines/acip/recs/grade/downloads/acip-evidence-recs-framework.pdf.

21. Centers for Disease Control and Prevention, Charter of the Advisory Committee on Immunization Practices, https://www.cdc.gov/vaccines/acip/committee/acip-charter.pdf.

22. Committee on Integrating Primary Care and Public Health; Board on Population Health and Public Health Practice; Institute of Medicine. Primary Care and Public Health: Exploring Integration to Improve Population Health, National Academies Press, Washington, D.C. (Mar. 28, 2012). Appendix A, Health Resources and Services Administration (HRSA) and Centers for Disease Control and Prevention (CDC), https://www.ncbi.nlm.nih.gov/books/NBK201596/.

23. Health Resources & Services Administration, Preventive Guidelines and Screenings for Women, Children, and Youth, https://mchb.hrsa.gov/programs-impact/programs/preventive-guidelines-screenings-women-children-youth.

24. Health Resources & Services Administration, Bright Futures, https://mchb.hrsa.gov/programs-impact/bright-futures.

25. 45 C.F.R. § 147.130(a)(1)(iv).

26. Women's Preventive Services Initiative, About WPSI, https://www.womenspreventivehealth.org/about-wpsi/.

27. Richard Hughes IV, Devon R. Minnick & Ada Peters, HRSA's Confusing, Out-of-Date Guidance Undermines Contraceptive Coverage and Access, Health Affairs Forefront (Sept. 28, 2022).

28. Health Resources & Services Administration, Advisory Committee on Heritable Disorders in Newborns and Children, https://www.hrsa.gov/advisory-committees/heritable-disorders.

29. Health Resources & Services Administration, History of the ACHNDC, https://www.hrsa.gov/sites/default/files/hrsa/advisory-committees/heritable-disorders/hrsa-timeline-interactive.pdf.

30. Health Resources & Services Administration, Recommended Uniform Screening Panel, https://www.hrsa.gov/advisory-committees/heritable-disorders/rusp.

31. Health Resources & Services Administration, Heritable Disorders—About the Committee, https://www.hrsa.gov/advisory-committees/heritable-disorders/about.

32. 42 U.S.C. § 299b-4(a)(6).

33. Lucia v. Sec. & Exch. Comm'n, 585 U.S. __ (2018).

34. Richard Hughes IV, William Walters & Nija Chappel, Will the U.S. Supreme Court Strike Down the ACA's Preventive Services Coverage Requirement?, Health Affairs Forefront (Sept. 23, 2022).

35. 42 U.S.C. § 299b-4(a)(1).

36. United States Preventive Services Task Force, USPSTF and Cost Considerations, https://www.uspreventiveservicestaskforce.org/uspstf/about-uspstf/task-force-resources/uspstf-and-cost-considerations.

37. Centers for Disease Control and Prevention, Charter of the Advisory Committee on Immunization Practices, https://www.cdc.gov/vaccines/acip/committee/acip-charter.pdf.

38. Women's Preventive Services Institute, Methodology, https://149858107.v2.pressablecdn.com/wp-content/uploads/WPSI-Methodology.pdf.

39. Health Resources & Services Administration, Bright Futures, https://mchb.hrsa.gov/programs-impact/bright-futures.

40. Health Resources & Services Administration, Condition Nomination and Review, https://www.hrsa.gov/advisory-committees/heritable-disorders/condition-nomination.

41. Alex H. Krist et al., Advancing the Methods of the U.S. Preventive Services Task Force, Am. J. Prev. Med. 54(1S1) (2018), S1.

42. Barron H. Lerner & Graham Curtiss-Rowlands, Evidence Over Politics—The U.S. Preventive Services Task Force, N. Engl. J. Med. 388(1), (Jan. 5, 2023), 4.

43. *Id.*

44. Tracy A. Wolff et al., Update on the Methods of the U.S. Preventive Services Task Force, Am. J. Prev. Med. 54(1S1) (2018), S12.

45. Stephanie C. Chen & Steven D. Pearson, Policy Framework for Covering Preventive Services Without Cost Sharing Saving Lives and Saving Money?, JAMA Intern. Med. 176(8) (Aug. 2016), 1185-1189, 1187, https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2530289.

46. United States Preventive Services Task Force, USPSTF and Cost Considerations, https://www.uspreventiveservicestaskforce.org/uspstf/about-uspstf/task-force-resources/uspstf-and-cost-considerations.

47. J. Frieden, Specialists, Generalists Face Off at Hearing on USPSTF—House Bill Would Require More Specialist Input into Task Force, MedPage Today (Nov. 30, 2016), https://www.medpagetoday.com/publichealthpolicy/publichealth/61760.

48. Barron H. Lerner & Graham Curtiss-Rowlands, Evidence Over Politics—The U.S. Preventive Services Task Force, N. Engl. J. Med. 388(1) (Jan. 5, 2023), 4-5.

49. Women's Preventive Services Institute, Methodology, p. 5, https://149858107.v2.pressablecdn.com/wp-content/uploads/WPSI-Methodology.pdf.

50. Stephanie C. Chen & Steven D. Pearson, Policy Framework for Covering Preventive Services Without Cost Sharing Saving Lives and Saving Money?, JAMA Intern. Med. 176(8) (Aug. 2016), 1185-1189, 1187, https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2530289.

51. Advisory Committee on Heritable Disorders in Newborns and Children, Summary: Report and Recommendations of the Pilot Studies Workgroup, https://www.hrsa.gov/sites/default/files/hrsa/advisory-committees/heritable-disorders/achdnc-pilot-studies-report-summary.pdf.

52. U.S. Preventive Services Task Force, Grade Definitions, https://www.uspreventiveservicestaskforce.org/uspstf/about-uspstf/methods-and-processes/grade-definitions.

53. Centers for Disease Control and Prevention, Shared Clinical Decision-Making Recommendations, https://www.cdc.gov/vaccines/acip/acip-scdm-faqs.html.

54. U.S. Food and Drug Administration, Birth Control Guide, https://www.fda.gov/media/150299/download.

55. Peng-Jun Lu, David Yankey, Benjamin Fredua, Alissa C. O'Halloran, Charnetta Williams, Lauri E. Markowitz & Laurie D. Elam-Evans, Association of Provider Recommendation and Human Papillomavirus Vaccination Initiation Among Male Adolescents Aged 13-17 Years—United States, J. of Pediatrics, 206 (2019), 33-41.e1, https://www.sciencedirect.com/science/article/pii/S0022347618315415.

56. Richard Hughes IV, Reed Maxim & Alessandra Fix, Vague Vaccine Recommendations May Be Leading to Lack of Provider Clarity, Confusion Over Coverage, Health Affairs Forefront (May 7, 2019).

57. A. Kempe, M.A. Allison, J.R. MacNeil, S.T. O'Leary, L.A. Crane, B.L. Beaty, L.P. Hurley, M. Brtnikova, M.C. Lindley, J.L. Liang, A.P. Albert & J.C. Smith, Knowledge and Attitudes Regarding Category B ACIP Recommendations Among Primary Care Providers for Children, Academic Pediatrics 18(7) ((2018)), 763-768, https://doi.org/10.1016/j.acap.2018.04.005.

58. Richard Hughes IV, Reed Maxim & Alessandra Fix, Vague Vaccine Recommendations May Be Leading to Lack of Provider Clarity, Confusion Over Coverage, Health Affairs Forefront (May 7, 2019); *see also* 45 C.F.R. § 147.30.

59. Centers for Disease Control and Prevention, Shared Clinical Decision-Making Recommendations, https://www.cdc.gov/vaccines/acip/acip-scdm-faqs.html.

60. Richard Hughes IV, Devon R. Minnick & Ada Peters, HRSA's Confusing, Out-of-Date Guidance Undermines Contraceptive Coverage and Access, Health Affairs Forefront (Sept. 28, 2022).

61. *Id.*

62. *Id.*

63. *Id.*

64. Centers for Medicare and Medicaid Services, Center for Consumer Information and Insurance Oversight, FAQs About Affordable Care Implementation 47 (July 19, 2021), https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-Part-47.pdf.

65. U.S. Preventive Services Task Force, Final Recommendation Statement: Prevention of Human Immunodeficiency Virus (HIV) Infection: Preexposure Prophylaxis (June 11, 2019), https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/prevention-of-human-immunodeficiency-virus-hiv-infection-pre-exposure-prophylaxis.

66. U.S. Preventive Services Task Force, Prevention of HIV Infection: Pre-Exposure Prophylaxis:Aan Update for This Topic Is in Progress (Dec. 2, 2022), https://www.uspreventiveservicestaskforce.org/uspstf/draft-update-summary/prevention-human-immunodeficiency-virus-hiv-infection-prep.

67. Richard Hughes IV, Why Are We Delaying Coverage of New HIV Prevention?, Health Affairs Forefront (Jan. 26, 2023).

68. U.S. Public Health Service, Preexposure Prophylaxis for the Prevention of HIV Infection in the United States—2021 Update, A Clinical Practice Guideline, https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf.

69. 42 U.S.C. § 299b-4(a)(1).

70. U.S. Preventive Services Task Force, Procedure Manual Section 2. Topic Selection, Prioritization, and Updating, https://www.uspreventiveservicestaskforce.org/uspstf/about-uspstf/methods-and-processes/procedure-manual/procedure-manual-section-2-topic-selection-prioritization-and-updating.

71. 21st Century Cures Act, Pub. L. No. 114-255, §§ 3091, 3092, 3093 (2016).

72. Coronavirus Aid, Relief, and Economic Security (CARES) Act, Pub. L. No. 116-136, § 4203 (2020).

73. U.S. Preventive Services Task Force, Screening for Hepatitis B Virus Infection in Adolescents and Adults: U.S. Preventive Services Task Force Recommendation Statement, JAMA 324(23) (2020), 2415-2422.

74. M.K. Weng, M. Doshani, M.A. Khan et al. Universal Hepatitis B Vaccination in Adults Aged 19-59 Years: Updated Recommendations of the Advisory Committee on Immunization Practices—United States, 2022, 71 MMWR Morb. Mortal. Wkly. Rep. 13 (2022), 477-483.

75. R.H. Hughes, C. Sloan, A. Vidulich, C. Chepigin, M. Aviña, Ending an Epidemic Requires Multiple Interventions: Considerations for Developing and Harmonizing HIV Preventive Recommendations, Health Affairs Forefront (Nov. 13, 2019).

76. Centers for Disease Control and Prevention, Charter of the Advisory Committee on Immunization Practices, https://www.cdc.gov/vaccines/acip/committee/acip-charter.pdf.

77. 42 U.S.C. § 228g-10(d).

78. *Id.*

79. Centers for Disease Control and Prevention, CDC Moving Forward Report, https://www.cdc.gov/about/organization/cdc-moving-forward-summary-report.html.