Virtual Meeting
(in lieu of meeting at the 2022 Spring National Meeting)

REGULATORY FRAMEWORK (B) TASK FORCE
Wednesday, March 23, 2022
12:30 – 2:00 p.m. ET / 11:30 a.m. – 1:00 p.m. CT / 10:30 a.m. – 12:00 p.m. MT / 9:30 – 11:00 a.m. PT

ROLL CALL

Vicki Schmidt, Chair
Sharon P. Clark, Vice Chair
Jim L. Ridling
Lori K. Wing-Heier
Peni Itula Sapini Teo
Ricardo Lara
Michael Conway
Andrew N. Mais
Trinidad Navarro
Karima M. Woods
David Altmair
Dean L. Cameron
Amy L. Beard
Doug Ommen
Eric A. Cioppa
Gary D. Anderson
Anita G. Fox
Grace Arnold
Chlora Lindley-Myers
Eric Dunning

Kansas
Kentucky
Alabama
Alaska
American Samoa
California
Colorado
Connecticut
Delaware
District of Columbia
Florida
Idaho
Indiana
Iowa
Maine
Massachusetts
Michigan
Minnesota
Missouri
Nebraska

New Hampshire
New Jersey
New Mexico
North Carolina
North Dakota
Northern Mariana Islands
Ohio
Oklahoma
Oregon
Pennsylvania
Rhode Island
South Dakota
Tennessee
Texas
Utah
Virginia
Washington
West Virginia
Wisconsin

Staff Support: Jolie H. Matthews/Jennifer R. Cook

AGENDA

1. Consider Adoption of its 2021 Fall National Meeting Minutes
   —Commissioner Vicki Schmidt (KS)

2. Consider Adoption of its Subgroup and Working Group Reports
   A. Accident and Sickness Insurance Minimum Standards (B) Subgroup
      —Laura Arp (NE) and Andrew Schallhorn (OK)
   B. Employee Retirement Income Security Act (ERISA) (B) Working Group
      —Robert Wake (ME)
   C. Mental Health Parity and Addiction Equity Act (MHPAEA) (B) Working Group
      —Erica Weyhenmeyer (IL)
D. Pharmacy Benefit Manager Regulatory Issues (B) Subgroup—TK Keen (OR)

3. Hear an Update on the Center on Health Insurance Reforms’ (CHIR’s) Work—Maanasa Kona (CHIR, Georgetown University Health Policy Institute)

4. Hear a Discussion on the Health Savings Account (HSA), High-Deductible Health Plan (HDHP), and Prescription Drug Copayment Accumulator Issue—Carl Schmid (HIV + Hepatitis Policy Institute) and Jeffrey M. Klein and Roy Ramthun (American Bankers Association (ABA) Health Savings Account (HSA) Council)

5. Discuss Any Other Matters Brought Before the Task Force—Commissioner Vicki Schmidt (KS)

6. Adjournment
Agenda Item #1

Consider Adoption of its 2021 Fall National Meeting Minutes
—Commissioner Vicki Schmidt (KS)
The Regulatory Framework (B) Task Force met Nov. 30, 2021. The following Task Force members participated: Michael Conway, Chair (CO); Glen Mulready, Vice Chair, represented by Mike Rhoads (OK); Lori K. Wing-Heier represented by Sarah Bailey (AK); Jim L. Ridling represented by William Rodgers and Yada Horace (AL); Peni Itula Sapini Teo represented by Elizabeth Perri (AS); Evan G. Daniels represented by Erin Klug (AZ); Andrew N. Mais represented by Jared Kosky (CT); David Altmayer represented by Chris Struk and Shannon Doheny (FL); Doug Ommen represented by Andria Seip (IA); Dean L. Cameron (ID); Dana Popish Severinghaus represented by Ryan Gillespie (IL); Amy L. Beard represented by Alex Peck (IN); Vicki Schmidt (KS); Sharon P. Clark (KY); Gary D. Anderson represented by Kevin Beagan (MA); Eric A. Cioppa represented by Timothy Schott and Joanne Rawlings-Sekunda (ME); Anita G. Fox represented by Sarah Wohlford (MI); Grace Arnold represented by Galen Benshoo and Sherri Mortensen-Brown (MN); Chlora Lindley-Myers (MO); Mike Causey represented by Ted Hamby (NC); Jon Godfrey represented by Chrystal Bartuska (ND); Eric Dunning represented by Laura Arp (NE); Chris Nicolopoulos represented by Michelle Heaton and Roni Karnis (NH); Marlene Caride represented by Philip Gennace (NJ); Judith L. French represented by Laura Miller and George McNab (OH); Andrew R. Stolfi represented by TK Keen (OR); Jessica K. Altman (PA); Larry D. Deiter represented by Jill Kruger and Candy Holbrook (SD); Cassie Brown represented by Rachel Bowden (TX); Scott A. White represented by Julie Blauvelt, Bob Grissom, and James Young (VA); Mike Kreidler represented by Molly Nollette and Jane Beyer (WA); Mark Afable represented by Nathan Houdek (WI); and Allan L. McVey represented by Joylynn Fix and Ellen Potter (WV).

1. **Adopted its Nov. 9 and Summer National Meeting Minutes**

The Task Force met Nov. 9 to adopt its 2022 proposed charges.

Mr. Keen made a motion, seconded by Ms. Kruger, to adopt the Task Force’s Nov. 9 (Attachment One) and July 28 (see NAIC Proceedings – Summer 2021, Regulatory Framework (B) Task Force) minutes. The motion passed unanimously.

2. **Adopted its Subgroup and Working Group Reports**

Mr. Keen made a motion, seconded by Commissioner Clark, to adopt the following reports: the Accident and Sickness Insurance Minimum Standards (B) Subgroup, including its Nov. 1 (Attachment Two), Oct. 4 (Attachment Three), Sept. 20 (Attachment Four), Aug. 23 (Attachment Five), Aug. 9 (Attachment Six), and July 26 (Attachment Seven) minutes; the Employee Retirement Income Security Act (ERISA) (B) Working Group, including its Oct. 8 (Attachment Eight) and July 30 (Attachment Nine), minutes; the Mental Health Parity and Addiction Equity Act (MHPAEA) (B) Working Group, including its Aug. 5 minutes (Attachment Ten); and the Pharmacy Benefit Manager Regulatory Issues (B) Subgroup. The motion passed unanimously.

3. **Heard a Presentation on the NSA Federal Regulations and Implications for the States**

Katie Keith (Out2Enroll) and Jack Hoadley (Georgetown University Health Policy Institute) presented on the recently issued federal No Surprises Act (NSA) interim final rules (IFR), interim proposed rules (IPR) and implications for the states.

Ms. Keith provided an overview of the NSA’s scope and its protections, including what types of plans it covers and where its protections apply for plan years beginning on or after Jan. 1, 2022. She said the NSA’s IFR was issued July 1 with an effective date of Sept. 13. The IFR was issued jointly by the U.S. Department of Labor (DOL), the U.S. Department of Health and Human Services (HHS), the U.S. Department of the Treasury (Treasury Department), and the U.S. Office of Personnel Management (OPM).

Ms. Keith said the IFR includes provisions focused on both patients and regulated entities. She explained that the patient-focused provisions outline how patients can calculate cost-sharing, include notice-and-consent waivers provisions, and establish a consolidated complaints process. The regulated entities-focused provisions outline how to calculate the qualifying payment amount and include disclosure requirements and provisions related to communications between insurers and providers.

Ms. Keith said the DOL, the HHS, the Treasury Department, and the OPM jointly issued IPR Sept. 10 concerns the submission of information about air ambulance services and the process the HHS will take to investigate and enforce NSA violations. She said the IPR highlights the states as being the primary enforcers for state-regulated insurers and providers. The DOL is the
primary enforcer for self-insured health plans. The federal government is backup enforcer if a state fails to substantially enforce. Ms. Keith said that it is anticipated that the federal agencies will provide enforcement letters to each state outlining provision-by-provision whether the state and federal government will enforce that particular NSA provision.

Ms. Keith said the DOL, the HHS, the Treasury Department, and the OPM jointly issued a second IFR Sept. 30. She said the major focus of this IFR is on the independent dispute resolution (IDR) process. Other provisions include requirements related to good-faith cost estimates for uninsured patients and patients who have insurance coverage but do not wish to submit a claim for services to their insurer and requirements related to the patient-provider dispute resolution process when cost estimates are wrong.

Mr. Hoadley detailed the major provisions in the first IFR. He discussed the scope of the NSA’s balance billing protections with respect to the types of payers and providers subject to its requirements. He explained that IFR sets out provisions to determine the qualifying payment amount (QPA) for purposes of the federal IDR process. The IFR spells out definitions and methodology for determining the QPA. It also includes additional provisions affecting the QPA, including minimizing the influence of outlier prices that could skew the QPA higher. Mr. Hoadley also explained that the IFR defines what a “specified state law” is for purposes of determining what method will be used to determine the amount of payment to an out-of-network provider, which could be either a payment standard or arbitration or a combination of both. The IFR also specifies that states with self-funded opt-in programs can maintain those programs. If state law does not apply, the NSA applies.

Mr. Hoadley discussed the different state approaches to determining QPAs. Some states take a hybrid approach using both a payment standard or rule and an IDR process. Other states use a payment statement standard only or an IDR process only. He also discussed the federal agencies’ requirements for entities conducting the IDR process to use in making payment determinations.

Mr. Hoadley reiterated that the IFR confirms that state departments of insurance (DOIs) are the primary enforcers of provisions that apply to insurers and fully insured health products. He also noted that state officials are responsible for enforcing the law against providers, but the HHS will enforce the NSA’s requirements in states that choose not to or that fail to substantially enforce the law. The DOL will enforce the NSA’s provisions for self-funded group health plans. Mr. Hoadley said that it is anticipated that the HHS will enter into collaborative enforcement agreements with many states. He said the IFR proposes a consolidated complaints process for patients and others.

Mr. Hoadley discussed provisions in the second IFR concerning the good-faith cost estimates for uninsured patients and patients who have insurance coverage but do not wish to submit a claim for services to their insurer and requirements related to the patient-provider dispute resolution process when cost estimates are wrong. He said the federal agencies are still working on federal rules for insured patients with respect to these provisions. It is anticipated these rules will be issued sometime in early 2022. He said that due to this delay in rulemaking, the federal agencies have agreed not to enforce these provisions during 2022, but entities subject to these provisions must still comply and adopt a good faith, reasonable interpretation of the law.

Mr. Hoadley discussed provisions in the NSA concerning data reporting and other mechanisms for purposes of determining the NSA’s effect on various health care-related factors, such as its effect on health care costs, provider networks, and provider consolidation. He noted that for the states having balance billing protection laws prior to the enactment of the NSA, analyses trying to determine those laws’ effect on similar health care-related factors is limited. Depending on the state approach taken to determine payment amount, some studies of these state laws indicate little impact, while others indicate mixed impacts.

Commissioner Conway asked about the good faith attempt to participate in a carrier’s network a provider can cite and use in the provider’s arguments for determining the appropriate QPA. He asked if this provision is tied to a specific carrier or the market, generally. Mr. Hoadley said he does not believe the IFR addresses that issue, but the provision most likely is tied to the specific carrier that is the subject of the arbitration process.

Commissioner Conway asked if the federal rules address the situation when a provider enters into the federal IDR process, but later it is determined that the plan involved is state-regulated and the state has its own IDR process. Mr. Hoadley said he believes the arbitrator, as one of its responsibilities, will screen cases and ultimately tell the parties they will need to use the state IDR process. He acknowledged that other situations could be more complex, including cases involving multiple state IDR processes. He said in such complex cases, the federal rules seem to indicate the federal IDR process would be used.

Mr. Keen asked about the notices the federal Centers for Medicare & Medicaid (CMS) sends out as part of its petition process about organizations applying to become a certified independent dispute resolution entity (IDRE). He noted that from a state insurance regulator’s perspective, the given short time frame included in the petition process and the sparse information CMS provides on these organizations make it hard to evaluate them. He asked if Mr. Hoadley or Ms. Keith had any thoughts on what
state insurance regulators should be looking in their evaluation of these applicants. Mr. Hoadley said he has no insight on the issue, but he said it would be important for the states to discuss whether any state is familiar with an applicant and provide their experiences with that organization to other states. Ms. Keith said that from her perspective, the certification criteria in the federal rules is quite strong, which could be evidenced by the fact that only a small number of organizations have applied to date. She said that from her experience in talking to the states, the states are looking for organizations that have medical and billing expertise and understand market dynamics, among other things. Commissioner Conway asked about the ability for the parties to challenge the choice of arbitrator. Mr. Hoadley said the federal rules contemplate the parties agreeing on a particular arbitrator, but if the parties cannot agree, the federal agencies would select. He said that he does not believe the federal rules provide for a party to object to the selected arbitrator, unless possibly due to a conflict-of-interest concern. Mr. Hoadley said that for some states that use the arbitration process, the state has a list of potential arbitrators, and the parties can object to one or more being selected, but the federal IDR process is not structured this way.

Commissioner Clark said that in reviewing the list of IDRE applicants to date, a few currently perform external review of appeals for Kentucky. She acknowledged that Kentucky would need to do a bit more research to determine how they are structured, but a few of these applicants could be comprised solely of health care providers, which could be problematic. She asked Mr. Hoadley and Ms. Keith if they had any thoughts on this issue. Mr. Hoadley said that he has not looked in depth as to how some of organizations applying to be IDREs are structured. He said that certainly an IDRE would need medical expertise and because of this, the IDRE would need to be aware of, and address, any actual or perceived conflicts of interest. He said these sorts of issues and ways to address them will evolve over time.

Commissioner Conway asked for those states that had a surprise bill law prior to the NSA and are now thinking about aligning these sorts of issues and ways to address them will evolve over time. and because of this, the IDRE would need to be aware of, and address, any actual or perceived conflicts of interest. He said that certainly an IDRE would need medical expertise and because of this, the IDRE would need to be aware of, and address, any actual or perceived conflicts of interest. He said these sorts of issues and ways to address them will evolve over time.

Commissioner Conway asked for those states that had a surprise bill law prior to the NSA and are now thinking about aligning the state law with the NSA, what provisions should the state focus on as part of this process. He said Colorado has focused on those provisions it thinks would be preempted by the federal law to avoid confusion. Mr. Hoadley agreed that there will be confusion about which law applies, state or federal, in some situations. He said the states may look at the types of services, providers, and facilities covered under their laws versus the NSA as provisions to focus on. Ms. Keith agreed. She said states also will have to think about retaining those provisions in their laws that are more protective, such as Colorado’s more protective ground ambulance provisions. Ms. Keith said one question has been raised is if those states with a state IDR process could opt to use the federal IDR process and as such, eliminate the need to maintain a parallel and potentially duplicative process. She said the federal agencies implementing the NSA have not been discussing this issue. Commissioner Conway agreed that in some cases, allowing an “opt-in” could be more efficient.

4. **Discussed Model #76 and the NSA**

Jolie Matthews (NAIC) said Section 110 of the NSA expands the scope of external review to include adverse benefit determinations related to disputes under the NSA, such as whether a plan or insurer complied with the NSA’s cost-sharing and other protections. She said that because the NSA applies to grandfathered health plans, external review extends to those plans as well. She explained that federal Affordable Care Act (ACA) requires non-grandfathered group health plans and insurers offering group and individual coverage to comply with state external review processes so long as those processes met certain standards. She said that to meet the ACA’s standards, state laws on external review must, at a minimum, reflect the consumer protections included in the Uniform Health Carrier External Review Model Act (#76), and external review must be available for adverse benefit determinations based on requirements for medical necessity, appropriateness, health care setting, level of care, or effectiveness of a covered benefit. She said the NSA expands the scope of the adverse benefit determinations currently provided under Model #76. She said the Task Force has at least four options to consider to address the issue: 1) substantively revise Model #76 to expand its scope to cover NSA disputes; 2) non-substantively revise Model #76, such as adding a drafting note alerting the states about the issue; 3) develop a memorandum or directive to the states to alerting them about the issue; or 4) take no action.

Commissioner Conway suggested that the Task Force form an ad hoc group to work with NAIC staff to develop a recommendation for the Task Force’s consideration to address the issue. There was no objection to his suggestion. Commissioner Conway asked Task Force members to send an email to NAIC staff expressing interest in serving on the ad hoc group. Ms. Matthews said she intends to have the ad hoc group meet sometime in January 2022 for it to make a recommendation to the Task Force on next steps in February.

Having no further business, the Regulatory Framework (B) Task Force adjourned.
Agenda Item #2

Consider Adoption of its Subgroup and Working Group Reports
—Commissioner Vicki Schmidt (KS)

- Mental Health Parity and Addiction Equity Act (MHPAEA) (B) Working Group
  —Erica Weyhenmeyer (IL)
- Accident and Sickness Insurance Minimum Standards (B) Subgroup—Laura Arp (NE)
- Employee Retirement Income Security Act (ERISA) (B) Working Group—Robert Wake (ME)
- Pharmacy Benefit Manager Regulatory Issues (B) Subgroup—Laura Arp (NE)
Virtual Meetings

MENTAL HEALTH PARITY AND ADDICTION EQUITY ACT (MHPAEA) (B) WORKING GROUP
March 1, 2022 / January 25, 2022

Meeting Summary Report

The Mental Health Parity and Addiction Equity Act (MHPAEA) (B) Working Group of the Regulatory Framework (B) Task Force met March 1 and Jan. 25, 2022. During these meetings, the Working Group met in regulator-to-regulator sessions pursuant to paragraph 8 (Consideration of strategic planning issues relating to federal legislative and regulatory matters) of the NAIC Policy Statement on Open Meetings.
Virtual Meetings

ACCIDENT AND SICKNESS INSURANCE MINIMUM STANDARDS (B) SUBGROUP
March 21, 2022 / March 7, 2022 / February 14, 2022 / December 6, 2021

Summary Report

The Accident and Sickness Insurance Minimum Standards (B) Subgroup of the Regulatory Framework (B) Task Force met March 21, March 7, and Feb. 14, 2022, and Dec. 6, 2021. During these meetings, the Subgroup:

1. Based on the comments received, discussed revisions to Sections 1-7 of the Model Regulation to Implement the Accident and Sickness Insurance Minimum Standards Model Act (#171).

2. Discussed its approach for reviewing and considering revisions to Model #171, including whether to begin its review of potential revisions for supplemental products first and then consider potential revisions for short-term, limited-duration (STLD) plans.
The Accident and Sickness Insurance Minimum Standards (B) Subgroup of the Regulatory Framework (B) Task Force met March 7, 2022. The following Subgroup members participated: Laura Arp, Co-Chair (NE); Andy Schallhorn, Co-Chair, represented by Cuc Nguyen, Landon Hubbart, and Rebecca Ross (OK); Debra Judy (CO); Howard Liebers (DC); Chris Struk (FL); Robert Wake (ME); Camille Anderson-Weddle (MO); Shari Miles (SC); Rachel Bowden (TX); Shelley Wiseman and Heidi Clausen (UT); and Ned Gaines (WA).

1. **Discussed Revisions to Model #171**

Jolie H. Matthews (NAIC) reviewed a revised draft of proposed revisions to the *Model Regulation to Implement the Accident and Sickness Insurance Minimum Standards Model Act (#171)* based on the Subgroup’s discussions to date. She highlighted some of the more substantive anticipated revisions, including: 1) adding a new section, Section 5—Definitions, to include terms used in the model; 2) adding language to Section 4—Applicability to address how revisions to the model will affect policies and contracts in effect prior to the date the revised model is adopted by the state; and 3) revisions to Section 6—Policy Definitions, formally Section 5, to address an insurer’s ability to alter the policy definitions, but only in a manner that does not restrict coverage. She also pointed out that many of the anticipated revisions reflect changes intended to make Model #171 consistent with its companion model, the *Supplementary and Short-Term Health Insurance Minimum Standards Model Act (#170)* (formerly known as the *Accident and Sickness Insurance Minimum Standards Model Act*). She explained that as part of its review, the Subgroup will have to review those suggested revisions for accuracy.

Ms. Bowden suggested that the Subgroup consider adding a definition of “excepted benefits” consistent with the federal definition for that term to the proposed new definitions section. She said having such a definition could possibly allow the use of it to distinguish it from short-term, limited-duration (STLD) plans. She said having this term could also assist in establishing the structure of Model #171 as not applying to major medical coverage. Chris Petersen (Arbor Strategies LLC) said currently, the term “excepted benefits” is not used in Model #171. Ms. Bowden agreed. She said her suggestion contemplates the Subgroup actively looking to use the term to address the issues she highlighted as it moves forward with its review of Model #171 and to help state departments of insurance (DOIs) align with federal regulations with respect to what products are considered excepted benefits. Mr. Petersen suggested that when the Subgroup reviews the product standards for the products regulated under Model #171, it considers whether the standards are consistent with the federal definition of “excepted benefits” instead of defining the term. The Subgroup discussed Ms. Bowden’s suggestion and the concept of “excepted benefits.” The Subgroup also discussed different plan designs submitted to the states for form filing approval that seem to blur what may be considered under federal law and regulations as an excepted benefit or a limited benefit type of coverage, particularly with respect to certain types of indemnity products and reference-based pricing.

Ms. Bowden reiterated that she would like the model revisions to be clear that if a product does not satisfy the excepted benefits structure, it is not an excepted benefit product. She said Model #171 needs to be clear on this, particularly given the emergence of innovative products that seem to blur the lines between major medical products and supplemental products. The Subgroup discussed adding a definition of “excepted benefits” as a placeholder until it completes its review of the product standard provisions. The Subgroup also discussed adding language in Section 7—Supplementary and Short-Term Health Insurance Minimum Standards for Benefits, specifically Section 7B—Hospital Indemnity or Other Fixed Indemnity Coverage, to address this issue. The
Subgroup also discussed the different treatment of individual products and group products in the federal rules and Model #171.

Ms. Arp said the issue of excepted benefits she has encountered most frequently concerns indemnity products. She asked for comments from stakeholders on a product structured as an indemnity product that looks like a charge master or fee schedule. Cindy Goff (American Council of Life Insurers—ACLI) noted that this type of product has been an issue since before the federal Affordable Care Act’s (ACA’s) enactment because of the desire by some companies to sell so-called “mini-meds,” which are no longer allowed to be sold. She urged the Subgroup to be cautious about including overly prescriptive language, such as limiting the number of benefits and other potentially restrictive product designs, in Model #171 given that it is a minimum standards model.

Ms. Arp asked the Subgroup to consider as it moves forward with its work whether: 1) the revisions should include language clarifying the scope of indemnity products and what reference pricing means in relation to these products; or 3) the Subgroup should not include such language to avoid potential unintended consequences of including such language because the issues with indemnity products are old long-standing issues, and as such, it would be better to leave Model #171 as is.

Ms. Bowden said the Subgroup should align the language in Model #171 on fixed indemnity plans with the federal regulations. She said whether the Subgroup should add clarifying language and how it should be added, such as in a drafting note or another approach, would be something the Subgroup could think about and decide later.

The Subgroup decided to continue its discussions on indemnity plans and other issues discussed during this meeting during its next meeting March 21. The Subgroup also plans to discuss as it moves forward with its work whether it wants to review the comments and consider revisions to Model #171 for supplemental products first and go back and consider revisions to Model #171 for STLD plans after completing that review.

Having no further business, the Accident and Sickness Insurance Minimum Standards (B) Subgroup adjourned.
The Accident and Sickness Insurance Minimum Standards (B) Subgroup of the Regulatory Framework (B) Task Force met Feb. 14, 2022. The following Subgroup members participated: Laura Arp, Co-Chair (NE); Andy Schallhorn, Co-Chair (OK); Chris Struk (FL); Robert Wake (ME); Camille Anderson-Weddle, Amy Hoyt, and Cynthia Amann (MO); Rachel Bowden (TX); Heidi Clausen (UT); Anna Van Fleet, Mary Block, Christine Menard-O’Neil, and Jamie Gile (VT); and Ned Gaines (WA).

1. Continued Discussion of Revisions to Model #171

The Subgroup continued its discussion of revisions to the Model Regulation to Implement the Accident and Sickness Insurance Minimum Standards Model Act (#171) based on the comments received, beginning with the policy definition of “preexisting condition” in Section 5L—Policy Definitions.

Ms. Arp acknowledged the Subgroup’s extensive discussion of this policy definition during its last meeting. She expressed a desire to find a middle ground on how to define “preexisting condition” for supplemental products and short-term, limited-duration (STLD) plans. The Subgroup discussed different approaches, including, for supplemental products, eliminating the so-called prudent layperson standard language in the definition and retaining the two-year look-back and developing a different policy definition of “preexisting condition” for STLD plans. After additional discussion, the Subgroup agreed, for supplemental products, to delete the prudent layperson standard language and consider developing another policy definition for “preexisting condition” for STLD plans.

The Subgroup discussed its approach for considering revisions to Model #171 after it completes its review and discussion of the comments received on Section 5—Policy Definitions. Ms. Arp asked for comments on whether the Subgroup moving forward should first discuss revisions to Model #171 in the context of supplemental products while keeping in mind whether and how the provisions would apply to STLD plans. The Subgroup discussed Ms. Arp’s suggestion. During the discussion, some stakeholders suggested that other types of products also would need to be considered separately, such as limited scope dental plans and disability income protection plans. The discussion also included how Model #171’s companion model, the Supplementary and Short-Term Health Insurance Minimum Standards Model Act (#170) (formerly known as the Accident and Sickness Insurance Minimum Standards Model Act), treats STLD plans differently from supplemental products. The Subgroup discussed different approaches. One approach discussed removing language from the policy definitions related to minimum standards and placing it in the substantive provisions for those products. Another approach discussed the possibility of developing different model regulations for the various products regulated under Model #170.

Ms. Arp reiterated her suggestion for the Subgroup to begin with the approach of focusing on supplemental products while keeping in mind the similarities or differences and application for other products, such as STLD plans. The Subgroup continued the discussion of possible approaches, including discussing whether the Subgroup needed to work on the STLD plan provisions first because there is already a regulatory framework for supplemental products. Some stakeholders agreed and suggested that as part of this work, the Subgroup look at whether a particular provision: 1) only applies to STLD plans; 2) only applies to supplemental products; or 3) applies to both types of products.
After additional discussion and to assist the Subgroup on deciding its approach in moving forward with its review, NAIC staff agreed to develop a working draft of Model #171 reflecting the Subgroup’s discussions to date. The Subgroup plans to discuss the working draft and continue its discussions on the approach to take for its discussions of revisions to Model #171 during its next meeting March 7.

Having no further business, the Accident and Sickness Insurance Minimum Standards (B) Subgroup adjourned.
The Accident and Sickness Insurance Minimum Standards (B) Subgroup of the Regulatory Framework (B) Task Force met Dec. 6, 2021. The following Subgroup members participated: Andy Schallhorn, Co-Chair (OK); Chris Struk (FL); Robert Wake (ME); Sherri Mortensen-Brown (MN); Camille Anderson-Weddle, Amy Hoyt, and Carrie Couch (MO); Gayle Woods (OR); Shari Miles (SC); Rachel Bowden (TX); Shelley Wiseman and Heidi Clausen (UT); Anna Van Fleet, Emily Brown, Mary Block, Christine Menard-O’Neil, and Jamie Gile (VT); Ned Gaines (WA); and Nathan Houdek and Jennifer Stegall (WI).

1. **Continued Discussion of Revisions to Model #171**

The Subgroup continued its discussion of revisions to the *Model Regulation to Implement the Accident and Sickness Insurance Minimum Standards Model Act* (#171) based on the comments received, beginning with the definition of “partial disability” in Section 5J. Jolie H. Matthews (NAIC) said after the Subgroup previously discussed the comments received on this definition, particularly the NAIC consumer representatives’ comments, the NAIC consumer representatives withdrew their comments, leaving the provision unchanged. The Subgroup confirmed the decision to leave Section 5J unchanged.

The Subgroup next discussed the definition of “physician” in Section 5K. Ms. Matthews said the Subgroup’s previous discussion of this provision concerned the perceived lack of clarity of some of the language in the definition and whether the Subgroup should try to clarify it. Mr. Schallhorn asked the Subgroup if anyone had any suggestions for clarifying the language. J.P. Wieske (Health Benefits Institute—HBI) said the intent of the language in Section 5K(2) is to address potential fraud by restricting certain individuals who may have a personal relationship with the insured from being considered a “physician” for the purposes of this model. In response to the Washington Department of Insurance’s (DOI’s) question about the meaning of the terms “qualified physician” and “licensed physician” in Section 5K(1), Mr. Wieske also said he believes this language is intended to restrict an insurer from raising an issue about certain providers, for the purposes of making a claim for any provider of medical care and treatment, if the services provided are within the scope of the provider’s licensed authority and are provided pursuant to applicable laws. After additional discussion, the Subgroup decided to leave the language unchanged.

The Subgroup next discussed the definition of “preexisting condition” in Section 5L. Ms. Matthews explained that the Subgroup’s previous discussions ended with this definition. She also noted that the Subgroup received additional comments on this definition as part of its request for comments on Sections 1–7 ending July 2. Mr. Schallhorn said America’s Health Insurance Plans (AHIP) suggests separate definitions of “preexisting condition” for supplementary products and short-term, limited-duration (STLD) plans. He asked for comments.

Mr. Wake said he believes there should be one definition of “preexisting condition” but different look-back periods for these two types of coverages. The Subgroup discussed his comments, including the implications of changing the definition on existing policies and contracts. Lucy Culp (Leukemia & Lymphoma Society—LLS) asked about the typical length of a look-back period, such as six months or 12 months. Mr. Wieske said for some types of products, it would probably be about a two-year look-back period. He explained that these types of products typically have limited medical underwriting. As such, the purpose of the look-back period is to protect against an individual purchasing, for example, a cancer-only policy when they knew they had cancer prior to the policy purchase.
The Subgroup discussed potential differences in the typical look-back period for supplementary products and STLD plans. Some interested parties favored a two-year look-back period for both types of coverages as a minimum standard. Other interested parties expressed support, generally, for shorter look-periods for all coverage types. Ms. Culp said the NAIC consumer representatives suggest a six-month look-back period. Chris Petersen (Arbor Strategies LLC) said based on the provisions in the Supplementary and Short-Term Health Insurance Minimum Standards Model Act (#170) (formerly known as the Accident and Sickness Insurance Minimum Standards Model Act), the companion model for Model #171, revising the definition of “preexisting condition” to provide for a six-month look-back period would not be possible. He said AHIP could support a two-year look-back period for supplementary products. For STLD plans, he said AHIP would be open to discussing a shorter look-back period because it is a different type of coverage; although, AHIP does not believe a shorter look-back period is needed. Cindy Goff (American Council of Life Insurers—ACLI) said the ACLI supports a two-year look-back period for supplementary products, but the ACLI has no position on STLD plans because none of its members sell such coverage.

The Subgroup continued its discussions regarding the look-back periods and the provision in Section 7A and Section 7B of Model #170 related to this issue. The Subgroup also discussed whether it should separate the look-back period provision from the policy definition of “preexisting condition” because it affects whether a condition is in fact a “pre-existing condition.” The Subgroup also discussed whether the preexisting condition policy definition should retain the prudent layperson standard. Some interested parties expressed concern with removing the prudent layperson standard if the look-back period is shortened to six months and the potential for abuse because of such a revision. The Subgroup discussed the Missouri DOI’s suggested revision that would remove the prudent layperson standard. The Subgroup did not reach any decisions on the issue and agreed to continue the discussion during its next meeting in early 2022.

Having no further business, the Accident and Sickness Insurance Minimum Standards (B) Subgroup adjourned.
Virtual Meetings

EMPLOYEE RETIREMENT INCOME SECURITY ACT (ERISA) (B) WORKING GROUP
March 22, 2022 / March 15, 2022

Summary Report

The Employee Retirement Income Security Act (ERISA) (B) Working Group of the Regulatory Framework (B) Task Force met March 22 and March 15, 2022. During these meetings, the Working Group:

1. Discussed exposing for a public comment period an update to the Health and Welfare Plans Under the Employee Retirement Income Security Act: Guidelines for State and Federal Regulation (ERISA Handbook) related to the U.S. Supreme Court’s decision in Rutledge vs. the Pharmaceutical Care Management Association (PCMA). Following this discussion, the Working Group adjourned into a regulator-to-regulator session, pursuant to paragraph 1 (Potential or pending litigation or administrative proceedings), paragraph 2 (Pending investigations), paragraph 3 (Specific companies, entities or individuals), paragraph 8 (Consideration of strategic planning issues relating to federal legislative and regulatory matters), and paragraph 9 (Any other subject required to be kept confidential under any Memorandum of Understanding or other agreement, state or federal law or under any judicial or administrative order) of the NAIC Policy Statement on Open Meetings.

2. Met in a regulator-to-regulator session pursuant to paragraph 1 (Potential or pending litigation or administrative proceedings), paragraph 2 (Pending investigations), paragraph 3 (Specific companies, entities or individuals), paragraph 8 (Consideration of strategic planning issues relating to federal legislative and regulatory matters), and paragraph 9 (Any other subject required to be kept confidential under any Memorandum of Understanding or other agreement, state or federal law or under any judicial or administrative order) of the NAIC Policy Statement on Open Meetings.
Summary Report

The Pharmacy Benefit Manager Regulatory Issues (B) Subgroup of the Regulatory Framework (B) Task Force met March 16. During this meeting, the Subgroup:

1. Adopted its 2021 Fall National Meeting minutes.

2. Heard an update from Montana on its pharmacy benefit manager (PBM) law.


4. Heard an update from NAIC staff on its work compiling state PBM laws and regulations related to the Subgroup’s 2022 charge to develop a white paper on issues related to the state regulation of certain PBM business.

5. Discussed plans for its meeting at the Spring National Meeting.
Pharmacy Benefit Manager Regulatory Issues (B) Subgroup
Virtual Meeting
March 16, 2022

The Pharmacy Benefit Manager Regulatory Issues (B) Subgroup of the Regulatory Framework (B) Task Force met March 16, 2022. The following Subgroup members participated: TK Keen, Chair (OR); Laura Arp, Vice Chair, and Eric Dunning (NE); Sarah Bailey (AK); Anthony L. Williams (AL); Beth Barrington (AR); Jessica Ryan (CA); Paul Lombardo and Kathy Belfi (CT); Howard Liebers (DC); Andria Seip (IA); Vicki Schmidt (KS); Daniel McIlwain (KY); Jeff Zewe (LA); Chad Arnold and Joe Stoddard (MI); Cynthia Amann and Amy Hoyt (MO); Sherri Mortensen-Brown and Norman Barrett Wiik (MN); David Dachs (MT); Ted Hamby and Robert Croom (NC); Ralph Boeckman and Erin Porter (NJ); Paige Duhamel (NM); Ana Paulina Gomez (PA); Katrina Rodon (SC); Brian Hoffmeister and Scott McAnally (TN); Tanji J. Northrup (UT); Don Beatty and Stephen Hogge (VA); Jennifer Kreitler and Ned Gaines (WA); Nathan Houdek and Jennifer Stegall (WI); Michael Malone and Ellen Potter (WV); and Jeff Rude and Bryce Hamilton (WY). Also participating was: Robert Wake (ME).

1. **Adopted its 2021 Fall National Meeting Minutes**

   Mr. Lombardo made a motion, seconded by Mr. Beatty, to adopt the Subgroup’s Dec. 11, 2021, minutes (Attachment -A). The motion passed unanimously.

2. **Heard an Update from Montana on its PBM Law**

   Mr. Keen said the Subgroup’s next agenda item is to hear from Montana about its pharmacy benefit manager (PBM) law and other related activities. He explained that the agenda has Oklahoma also providing an update, but due to unforeseen circumstances, Oklahoma will provide that update during the Subgroup’s meeting at the Spring National Meeting.

   Mr. Dachs discussed Montana’s PBM law and related activities over the past few years beginning with the U.S. Senate (Senate) Bill 71, which the Montana Legislature passed with bipartisan support in 2019, but it was vetoed by the governor. He explained that one central provision in Senate Bill 71 was to set up a mechanism to lower the cost of health insurance for consumers. The provision required that all compensation remitted by or on behalf of a manufacturer, labeler, repackager, or wholesale distributor that is directly or indirectly related to a health benefit plan be remitted to and retained by the health benefit plan and used to lower health benefit plan premiums for covered persons. Mr. Dachs explained that this provision was really aimed at spread pricing and trying to ensure consumers received a share of those remitted monies to lower their health insurance premiums. He said Senate Bill 71 reflected Montana’s approach to PBM regulation, which is different than what other states were doing at the time by focusing on the financial aspects of the prescription drug supply chain and looking at areas where it may be able to lower costs.

   Mr. Dachs said after its experience with Senate Bill 71 and a change in leadership at the Montana Department of Insurance (DOI), it has taken a more measured approach. He said like many other states, Montana decided to clarify its regulatory authority over PBMs and require that PBMs be licensed in the state. He said Montana also decided to focus on price transparency. In 2021, the Montana Legislature passed the Montana Pharmacy Benefit Manager Oversight Act, which became effective Jan. 1. Mr. Dachs said the bill establishes a PBM licensing requirement and includes other provisions, including some reporting requirements and prohibited practices. He said Montana believes this legislation is something it can build on as it moves forward. He discussed developing
regulations related to the licensing requirements, including network adequacy requirements. He said he anticipates Montana will end up licensing about 20 PBMs.

Mr. Dachs said based on its work related to Senate Bill 71, Montana found that due to contractual requirements, it was difficult for pharmacists to share information with the Montana DOI on what was in their contracts to facilitate investigating complaints. To address this—i.e., the recently enacted statute—the prohibited practices provision includes language allowing pharmacists to share information with the Montana DOI when it is investigating issues related to PBM business practices. Mr. Dachs outlined the Montana DOI’s steps for moving forward with promulgating regulations to implement the recently enacted law.

Mr. Keen asked Mr. Dachs if the Montana law includes any exemptions from the PBM licensing requirements or the reporting of data. Mr. Dachs said he does not believe there are any specific exemptions. He explained how the law is structured and how terms are defined. He said given this structure, some types of entities are automatically carved out. Ms. Seip asked about Montana’s PBM network adequacy requirements and how the Montana DOI determines the accuracy of a PBM’s compliance. Mr. Dachs said the Montana DOI has a template of community pharmacies that it uses. He explained that in some areas in Montana, there may not be pharmacies. In those situations, the Montana DOI will use a health carrier’s GeoAccess plan in addition to looking at where the plan enrollees are located, and the community pharmacies are located to access network adequacy. Mr. Dachs explained that to not stifle innovation, particularly innovation that could lower costs for consumers, the Montana DOI regulations allow for flexibility if a health benefit plan wants to have a narrow network, but the hope is that health benefit plans include at least 80% of the community pharmacies.

3. **Heard an Update from the ERISA (B) Working Group**

Mr. Wake provided an update on the work of the Employee Retirement Income Security Act (ERISA) (B) Working Group related to its revisions to the *Health and Welfare Plans Under the Employee Retirement Income Security Act: Guidelines for State and Federal Regulation* (ERISA Handbook) to include a case summary on the U.S. Supreme Court’s decision in *Rutledge vs. the Pharmaceutical Care Management Association (PCMA)*. He said the Working Group plans to meet March 22 to discuss an initial draft of the case summary. He anticipates that after that review and discussion, the Working Group will expose the draft for a public comment period.

Mr. Wake said as part of its work in 2022, the Working Group will provide its expertise to the Subgroup, as the Subgroup considers necessary, related to the *Rutledge* decision in relation to the Subgroup’s 2022 charge to develop a white paper discussing state laws regulating PBM business practices, including the implications of the *Rutledge* decision on such business practices and any challenges, if any, the states have encountered in implementing such laws and/or regulations.

Mr. Keen said the Subgroup welcomes the Working Group’s assistance and expertise as it moves forward with the white paper, including an analysis of the *Rutledge* decision, including its progeny and impact, if any, on the state regulation of PBM business practices. He said this collaboration is important to ensure consistency in any conclusions related to the *Rutledge* decision across NAIC groups.

4. **Heard an Update on State PBM Law Compilation**

Jolie H. Matthews (NAIC) said along with the Subgroup’s meeting agenda for today, she distributed two charts: 1) a compilation of state PBM licensing and registration laws; and 2) a compilation of state PBM business practice laws. She said these state PBM law compilations relate to and are meant to support the Subgroup’s efforts to complete its 2022 charge to develop a white paper on issues related to the state regulation of certain PBM business practices. She said she received corrections and updates to the charts for inclusion in the next versions
of each chart. She said she hopes to complete the updated versions sometime in late April or early May. She requested additional information from stakeholders on any missing state PBM laws to include in the updated versions.

Ms. Matthews said she has posted the compilation charges on the Subgroup’s web page under a new heading “State PBM Laws Charts.” She said she anticipates updating each chart moving forward on at least a quarterly basis, and the updated charts will be posted at this location on the Subgroup’s web page.

5. Discussed its Spring National Meeting Agenda and Future Meetings

Mr. Keen discussed the Subgroup’s agenda for its April 4 meeting during the Spring National Meeting and an outline for the Subgroup’s next few meetings. He said in addition to receiving an update from Oklahoma on its PBM law implementation, for the April 4 meeting, the Subgroup will hear a consumer perspective on the Subgroup’s white paper charge. The Subgroup will also hear from Oregon on some of its work related to prescription drug pricing transparency and prescription drug supply chain issues. Mr. Keen said the Subgroup will also hold level-setting and background meetings over the next few months to hear from speakers suggested by Subgroup members. He said the goal of these meetings is to ideally have the Subgroup begin its work drafting the white paper with a common level of understanding and knowledge about the issues to be discussed in the white paper.

6. Discussed State Pharmacy Complaint Processes

Mr. Hamilton said Wyoming has seen a recent rise in complaints from pharmacies alleging violations of certain provisions of its existing laws. He asked if any states set up a formal adjudication process to handle pharmacy complaints, including developing and using a specific template for such complaints. He explained that under Wyoming’s existing laws, it has a maximum allowable cost (MAC) appeals law and a law on pharmacy audit procedures.

Mr. Keen said Oregon has not received a high volume of such complaints. Mr. Beatty said for complaints from pharmacies, when Virginia first enacted its law, it did not receive a large volume of complaints because pharmacists found its website too complicated to file such complaints. He said to address this problem, Virginia developed a specific complaint form for pharmacists.

Mr. Hamilton asked that if anyone else has any information to assist Wyoming in developing a formal adjudication process to handle pharmacist complaints, he would appreciate it if they would reach out to him. Mr. Hogge said in addition to Virginia, Ohio and Oklahoma have developed specific pharmacist complaint forms. He suggested that as a starting point, Mr. Hamilton should look at what these states have done.

Having no further business, the Pharmacy Benefit Manager Regulatory Issues (B) Subgroup adjourned.
The Pharmacy Benefit Manager Regulatory Issues (B) Subgroup met in San Diego, CA, Dec. 11, 2021. The following Subgroup members participated: TK Keen, Chair (OR); Laura Arp, Vice Chair, and Martin Swanson (NE); Lori K. Wing-Heier (AK); Yada Horace (AL); Alan McClain (AR); Bruce Hinze (CA); Paul Lombardo and Kathy Belfi (CT); Andria Seip (IA); Julie Holmes (KS); Shawn Boggs (KY); Jeffrey Zewe (LA); Kathleen A. Brrane and Mary Kwei (MD); Chad Arnold (MI); Chlora Lindley-Myers and Cynthia Amann (MO); Tracy Biehn (NC); Gale Simon (NJ); Paige Duhamel (NM); Shannen Logue (PA); Brian Hoffmeister (TN); Tanji J. Northrup (UT); Don Beatty (VA); Molly Nollette (WA); Jonathan Houdek and Jennifer Stegall (WI); Joylynn Fix (WV); and Denise Burke (WY). Also participating were: David Altmaier (FL); Jon Godfread (ND); and Glen Mulready and Kelli Price (OK).

1. **Heard an Update on the Pharmaceutical Care Management Association v. Wehbi Ruling**

   Commissioner Godfread updated the Subgroup on the recent decision by the Eighth Circuit of the U.S. Court of Appeals in *Pharmaceutical Care Management Association v. Wehbi*. He said the Eighth Circuit’s decision upheld two laws enacted during North Dakota’s 2017 legislative session. These laws were enacted as an effort to prohibit pharmacy benefit managers (PBMs) from engaging in what have been considered deceptive and anti-competitive practices, which ultimately drive up prescription drug costs. The *Pharmaceutical Care Management Association v. Wehbi* case is the first to consider at the federal appellate level the scope of the U.S. Supreme Court’s unanimous decision last year in *Rutledge v. Pharmaceutical Care Management Association*, which upheld an Arkansas state law regulating the abusive practices of PBMs.

   Commissioner Godfread said based on the North Dakota Department of Insurance’s (DOI’s) legal analysis of the *Pharmaceutical Care Management Association v. Wehbi* decision, the North Dakota DOI believes the *Pharmaceutical Care Management Association v. Wehbi* decision significantly expands upon the *Rutledge v. Pharmaceutical Care Management Association* decision, which provided a framework that places a broader category of laws presumptively beyond the Employee Retirement Income Security Act’s (ERISA’s) preemptive scope—i.e., health care cost regulation—including state legislation regulating PBMs in this area. He said *Pharmaceutical Care Management Association v. Wehbi* took that a step further to uphold laws regulating PBMs against ERISA preemption where the laws regulate matters of transparency; the imposition of fees, fines, and arbitrary performance metrics; and other requirements upon pharmacy providers, thereby preventing anti-competitive practices by PBMs. He said he believes the *Rutledge v. Pharmaceutical Care Management Association and Pharmaceutical Care Management Association v. Wehbi* decisions now open the door for states to pass more laws that regulate PBMs more comprehensively and have those laws upheld as applied to ERISA plans, as long as the laws pass the ERISA “tests” established in these cases.

   Mr. Keen thanked Commissioner Godfread for bringing the *Pharmaceutical Care Management Association v. Wehbi* decision to the Subgroup’s attention. He said he believes the Subgroup will find the North Dakota DOI’s analysis of the case helpful as it moves forward with its work to develop a white paper on issues related to the state regulation of certain PBM business practices. He also said he assumes the ERISA (B) Working Group will be examining the *Pharmaceutical Care Management Association v. Wehbi* decision as well. As such, the Subgroup will coordinate its discussions on the case with the Working Group.

2. **Heard from the States on the Implementation of PBM Laws**

   Mr. Keen said the Subgroup’s next agenda item is to hear from Connecticut, Oklahoma, Virginia, and Wisconsin on their PBM laws. He said this agenda item was added at the request of Subgroup members wanting to know what other states have done with respect to PBM regulation and oversight. He said he believes this information will be helpful to the Subgroup as it moves forward with the white paper and potentially for additional Subgroup discussions about developing another draft PBM model.

   a. **Connecticut**

      Mr. Lombardo discussed Connecticut’s PBM law. He said Connecticut requires PBMs to register with the state. He discussed Connecticut Gen Stat § 38a-479ppp (2019), which was enacted under Public Act 18-41. He said this statute requires PBMs for insured business in the state to file a report each year with the commissioner that includes information on the aggregate dollar amount of all rebates for outpatient prescription drugs the PBM collected from pharmaceutical manufacturers and the aggregate
dollar amount of all rebates for outpatient prescription drugs, excluding any portion of the rebate received by health carriers, the PBM collected from the pharmaceutical manufacturers. He said Connecticut received the first of this data at the beginning of 2020 and will receive the second set of data at the beginning of 2022. He said this information will be made public sometime in the first quarter of 2022. He said although not strictly related to PBMs, Public Act 18-41 also requires health insurers to provide information on their rebate practices. He said based on this information, the commissioner prepares an annual report, which is posted on the DOI’s website, containing: 1) an explanation of the manner in which health carriers accounted for rebates in calculating premiums for health care plans delivered, issued for delivery, renewed, amended, or continued during such year; 2) a statement disclosing whether, and describing the manner in which, health carriers made rebates available to insureds at the point of purchase during such year; 3) any other manner in which health carriers applied rebates during such year; and 4) such other information as the commissioner, in the commissioner’s discretion, deems relevant. He also discussed a provision in Connecticut law modeled after a California law requiring health insurers as part of their rate filing to provide data on prescription drugs; i.e., the top 25 most costly drugs and the top 25 most utilized drugs.

Ms. Belfi discussed Connecticut’s review of affiliated agreements health insurers have with PBMs as part of the DOI’s financial analysis requirements of the companies. Mr. Lombardo explained that as part of this financial analysis work, the Connecticut DOI realized it needs to learn more about every aspect of the prescription drug distribution system, which ultimately resulted in a draft, non-public white paper that Connecticut has shared with the Subgroup. He noted that as part of this process, the Connecticut DOI came to realize the possibility of unintended consequences of any PBM legislation meant to address one aspect of PBM business practices, such as rebating, on other aspects of the prescription drug distribution system.

b. Oklahoma

Ms. Price discussed Oklahoma’s Patient’s Right to Pharmacy Choice Act, which was effective Nov. 1, 2019. She explained that the Act establishes minimum and uniform access to a provider and standards and prohibitions on restrictions of a patient’s right to choose a pharmacy provider. These minimum standards include provisions: 1) barring PBMs from reimbursing independent pharmacies at a lesser amount than PBM-owned pharmacies; 2) outlining geographical requirements for urban, suburban, and rural pharmacy access; and 3) prohibiting incentives related to mail-order, cost-sharing, co-payments, or other discounts. She explained how the Rutledge v. Pharmaceutical Care Management Association case and, ultimately, the U.S. Supreme Court’s decision in that case affected the Oklahoma DOI’s implementation and enforcement of the Act.

Ms. Price also discussed the Oklahoma DOI’s initiatives related to ensuring PBM compliance and enforcement of the Act. She said the Oklahoma DOI created a division focused solely on PBM compliance and enforcement. It hired staff, including an industry expert/pharmacist consultant, with the applicable knowledge and expertise in these areas. Ms. Price said the Oklahoma DOI created a process on its website for consumers to submit complaints about PBMs online. As part of this, and to make the process as smooth as possible, the division developed templates for typical correspondence sent to PBMs and consumer complainants, including a “blue sheet” specific to PBM alleged violations, which can be used for Oklahoma DOI investigators to succinctly summarize their investigations and more quickly refer cases to the legal division for enforcement actions. Based on the Oklahoma DOI’s experiences, Ms. Price also offered suggestions to states considering PBM legislation and currently implementing PBM laws.

Ms. Price said since Sept. 1, 2020, the Oklahoma DOI has received and reviewed over 135,000 alleged violations of the Act. She said approximately 27,000 have been resolved to date, and 32 alleged violations have been referred to the Oklahoma legal division for an enforcement action.

Mr. Houdek asked Ms. Price if staff hired for the new division were newly hired staff or repurposed staff. Ms. Price said it was a combination of new staff and repurposed staff. Mr. Houdek asked Ms. Price about the nature of complaints filed. Ms. Price said most of the complaints related to transaction fee issues and maximum allowable cost (MAC) pricing appeals and reimbursement amounts. Ms. Price asked about the fiscal note attached to the Act. Commissioner Mulready said such a fiscal note would have been approximately $500,000 from the Oklahoma DOI’s perspective. Ms. Duhamel asked about the MAC appeals. Ms. Price described how the Oklahoma DOI has uncovered such violations. She explained that the pharmacy services administrative organizations (PSAOs) have alerted the Oklahoma DOI about alleged MAC pricing appeal violations.

c. Virginia

Mr. Beatty discussed Virginia’s PBM law, which was effective Oct. 1, 2020. He explained that Virginia’s PBM law places the responsibility on the health insurer for compliance with the law. Under the law, PBMs must be licensed. Mr. Beatty explained that if the PBM fills out the application correctly, the PBM law requires the Virginia DOI to issue the license. He described the PBM law’s prohibitions on certain conduct by a health carrier or by a PBM under contract with a carrier. These prohibitions
include: 1) reimbursing a pharmacy or pharmacist an amount less than the amount the PBM reimburses a PBM affiliate for providing the same pharmacist services; and 2) penalizing or retaliating against a pharmacist or pharmacy for exercising rights provided under the law. He said the Virginia law also prohibits a health carrier or a PBM under contract with a carrier from: 1) including any mail order pharmacy or PBM affiliate in calculating or determining network adequacy; and 2) conducting spread pricing.

Mr. Beatty said currently, Virginia has 39 licensed PBMs. He said the Virginia DOI has not received a lot of complaints related to its law. He explained that because of this seemingly lack of complaints, the Virginia DOI decided to create and post on its website a specific complaint form that can be used to file complaints related to the PBM law. He said even with the specific complaint form, the Virginia DOI still has not received a lot of complaints specific to the PBM law.

Mr. Beatty also described Virginia’s quarterly reporting requirements related to rebates and its examination requirements. He said the Virginia DOI plans to submit legislation for consideration during the 2022 legislative session changing the quarterly rebate reporting requirements to an annual report since the Virginia DOI will not review the information until the end of each calendar year.

Ms. Arp asked Mr. Beatty about the confidentiality of the examination reports and the fee for such examinations. Mr. Beatty described the Virginia law’s confidentiality requirements, which is consistent with the NAIC’s model confidentiality language regarding examination reports and any working papers, documents, reports, and other information compiled during an examination. He explained that the Virginia DOI does not charge companies for financial or market conduct examinations. The money to pay for examinations comes from the Virginia DOI’s general assessment.

d. Wisconsin

Mr. Houdek discussed the work of the Governor’s Task Force on Reducing Prescription Drug Prices before Wisconsin’s proposed PBM law was introduced. He said the Task Force held eight public meetings from November 2019 to August 2020. The Task Force heard from 24 organizations representing a multitude of stakeholders. He said the Task Force issued a report in October 2020, which centered on the following key policy provisions: 1) lowering prices and controlling costs; 2) increasing transparency and consumer protections; and 3) access for vulnerable populations.

Mr. Houdek said with respect to increasing transparency and consumer protections, among its recommendations, the Task Force recommended the creation of the Office of Prescription Drug Affordability. He said similar to Oklahoma’s approach, the Task Force recognized that the Wisconsin DOI does not have the capacity and appropriate expertise to implement and enforce the requirements for a law regulating PBMs and the prescription drug market.

Mr. Houdek said 20 of the Task Force’s recommendations were included in the governor’s 2021–2023 biennial budget. He said during the budget process, the Task Force’s recommendations were removed and introduced as separate, stand-alone bills and packaged as “Less for Rx.” However, due to the COVID-19 public health emergency and other circumstances, the PBM legislation died during the 2020 legislative session. Mr. Houdek said a slimmed down version of what was initially introduced was introduced in January 2021 and enacted in March 2021 (2021 Wisconsin Act 9). Key provisions in the law include: 1) a prohibition on gag clauses; 2) an annual PBM rebate reporting requirement; 3) a PBM licensure requirement; and 4) limitations on a PBM’s ability to retroactively deny or reduce a pharmacy’s claim after adjudication.

Mr. Houdek discussed the Wisconsin DOI’s next steps, which include: 1) tracking complaints and correspondence received; 2) learning from the efforts of other states as they implement their PBM oversight laws; and 3) continuing to work with stakeholders to build support to advance the other Task Force recommendations. He also said the fiscal note for the initial PBM bill included: 1) seven new staff; and 2) $500,000 in information technology (IT) upgrades. He said this fiscal note request was attached to the January 2021 legislation; but ultimately, the Wisconsin DOI received no new dollars to assist with implementation and enforcement. He said the Wisconsin DOI’s market regulation division has been tasked with implementing the new PBM law and has been working over the past few months to create a dedicated website and develop complaint templates, consumer-facing materials, and other information necessary for a smooth implementation process.

3. Discussed its Next Steps

Mr. Keen said the Subgroup will continue its discussions on its white paper charge during a meeting early next year.

Having no further business, the Pharmacy Benefit Manager Regulatory Issues (B) Subgroup adjourned.
Agenda Item #3

Hear an Update on the Center on Health Insurance Reforms’ (CHIR’s) Work
—Maanas Kona (CHIR, Georgetown University Health Policy Institute)
Update on Georgetown CHIR’s Recent and Forthcoming Work

National Association of Insurance Commissioners Regulatory Framework (B) Task Force
March 23, 2022

Maanasa Kona, J.D.
Assistant Research Professor
Georgetown University Center on Health Insurance Reforms (CHIR)

Nationally recognized team of private insurance experts

- Part of McCourt School of Public Policy
- Legal & policy analysis
  - Federal and state regulation
  - Market trends
- Published reports, studies, blog posts
- Technical assistance
Implementation of the No Surprises Act

- State Protections for Ground Ambulance Surprise Bills
- New interactive map on the roles of federal and state officials on various aspects of the No Surprises Act:
  - Issuer Enforcement
  - Provider Enforcement
  - Interaction b/w Federal and State Balance Billing Laws
- Upcoming: Issue brief based on interviews with 12 state DOIs on their approaches to NSA implementation
Impacts of COVID-19

• State Preparations for the End of the PHE
  • Based on Interviews with Medicaid and SBM Officials from 11 States

• Lack of Compliance with COVID-19 Testing Coverage Mandates

• Impact of COVID-19 on Small Business Health Insurance
Alternative Coverage Issues

• Misleading Marketing of Non-ACA Health Plans During COVID-19 Special Enrollment Period

• Massachusetts Data on Health Care Sharing Ministries Reveal Finances That Put Consumers at Risk
Enrollment and Coverage

• State “Easy Enrollment” Programs Gain Momentum and Lay Groundwork for Additional Efforts to Expand Coverage

• Upcoming:
  • SBM outreach & advertising efforts during the most recent OEP
  • State Spotlight on California
Other Reading

• Leveraging the New Federal Health Care Transparency Rules to Contain Costs
• Network Adequacy Standards and Oversight
• Upcoming:
  • Comparing Network Adequacy Rules Across Marketplaces and Medicaid MCOs
  • State Efforts to Improve MHPAEA Compliance
  • SBM Efforts to Improve Health Equity
Questions?

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Agenda Item #4

Hear a Discussion on the Health Savings Account (HSA), High-Deductible Health Plan (HDHP), and Prescription Drug Copayment Accumulator Issue—Carl Schmid (HIV + Hepatitis Policy Institute) and Jeffrey M. Klein and Roy Ramthun (American Bankers Association (ABA) Health Savings Account (HSA) Council)
Copay Accumulators, State Bans & IRS Issues

Carl Schmid
Executive Director
HIV+Hepatitis Policy Institute
NAIC Consumer Representative

NAIC Regulatory Framework Task Force
March 23, 2022
Personal Healthcare Spending – 2019

- **3%** Hospital care
  - Out of Pocket: $36B
  - Total: $1,192B

- **7.8%** Physician, clinical services
  - Out of Pocket: $61B
  - Total: $772B

- **14.5%** Retail medicines
  - Out of Pocket: $54B
  - Total: $370B

Other Care
- Out of Pocket: $6B
- Total: $194B

Nursing care, retirement facilities
- Out of Pocket: $46B
- Total: $173B

Dental services
- Out of Pocket: $60B
- Total: $143B

Home health care
- Out of Pocket: $13B
- Total: $114B

Other services
- Out of Pocket: $27B
- Total: $111B

Non-durable medical products
- Out of Pocket: $80B
- Total: $82B

Durable medical equipment
- Out of Pocket: $26B
- Total: $58B

Increasing Deductibles

Median QHP Deductibles – Silver Level

The PY22 silver plan median deductible is $5,155, which is an increase of 6% from PY21 and 23% from PY18.

Patient Affordability Study

- About a third (32%) of single-person households with private insurance in 2019 could not pay a $2,000 bill, and half (51%) could not pay a $6,000 bill.

- Over 40% of multi-person households can't cover a mid-range employer family plan deductible of $4,000, and 61% don't have enough to cover a high-range deductible.

- With an average out-of-pocket maximum for single coverage of $4,272 in 2021 the study concludes: “Most households do not have enough liquid assets to meet the typical out-of-pocket maximum.”

Cost-Sharing and Rx Abandonment

Patients starting new therapy abandoned 55 million prescriptions at pharmacies in 2020 with increasing frequency as costs rise.

Exhibit 45: 14-day Abandonment Share of New-to-Product Prescriptions by Final Out-of-Pocket Cost in 2020, All Payers, All Products

Source: IQVIA LAAD Sample Claims Data, Dec 2020
Role of Copay Assistance

Patient Out-of-Pocket Cost for Prescriptions in Aggregate and Value Offset by Coupons, $Bn

Source: IQVIA National Prescription Audit, Formulary Impact Analyzer, Jan 2019
Chart notes: OOP (out-of-pocket) costs estimated based on prescription volumes and observed OOP costs. OOP costs projected from sample in FIA to a national estimate using national adjusted prescriptions which were backprojected to estimate the trend prior to the trend break after 2016 due to restatement of NPA volumes (see Methodology section for more details).
National Overview
Percent of Plans in States with Copay Accumulator Policies
Patient Scenarios

### Scenario 1: Plan *Without* a Copay Accumulator Program

<table>
<thead>
<tr>
<th></th>
<th>Jan</th>
<th>Feb</th>
<th>Mar</th>
<th>Apr</th>
<th>May</th>
<th>Jun</th>
<th>Jul</th>
<th>Aug</th>
<th>Sep</th>
<th>Oct</th>
<th>Nov</th>
<th>Dec</th>
<th>Total</th>
<th>Insurer collects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Copay Assistance</td>
<td>$1,680</td>
<td>$1,680</td>
<td>$1,240</td>
<td>$840</td>
<td>$840</td>
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<td>$0</td>
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<td>$0</td>
<td>$8,550</td>
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</tr>
<tr>
<td>Consumer Pays</td>
<td>$0</td>
<td>$0</td>
<td>$0</td>
<td>$0</td>
<td>$0</td>
<td>$0</td>
<td>$760</td>
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<td>$0</td>
<td>$0</td>
<td>$0</td>
<td>$0</td>
<td>$1,350</td>
<td>$1,350</td>
</tr>
</tbody>
</table>

**Deductible is met**  **Copay assistance limit is met**  **Out-of-Pocket maximum is met**

### Scenario 2: Plan *With* a Copay Accumulator Program

<table>
<thead>
<tr>
<th></th>
<th>Jan</th>
<th>Feb</th>
<th>Mar</th>
<th>Apr</th>
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<th>Jul</th>
<th>Aug</th>
<th>Sep</th>
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<th>Nov</th>
<th>Dec</th>
<th>Total</th>
<th>Insurer collects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Copay Assistance</td>
<td>$1,680</td>
<td>$1,680</td>
<td>$1,680</td>
<td>$1,680</td>
<td>$480</td>
<td>$0</td>
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<tr>
<td>Consumer Pays</td>
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<td>$0</td>
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<td>$0</td>
<td>$1,200</td>
<td>$1,680</td>
<td>$1,680</td>
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<td>$840</td>
<td>$840</td>
<td>$840</td>
<td>$840</td>
<td>$7,980</td>
<td>$7,980</td>
</tr>
</tbody>
</table>

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**THE AIDS INSTITUTE**
State Enacted Laws

Source: Aimed Alliance
States with Active Legislation to Address Accumulator Adjustment Programs

March 2022
Perceived Conflicts with IRS Law

▶ IRS FAQ (2004-pre ACA)
  - Pertains to Employers who offer **drug discount cards (which reduce overall price of the drug)**

▶ IRS Letter to Illinois (2021)
  - Equated drug discount to copay assistance (which changes *how* you pay and not the price of the drug)
  - “*may still contribute* to an HSA provided that the individual is required to pay the costs of the covered health care until the minimum annual deductible for the HDHP is satisfied”
State Actions

- **Illinois Bulletins (2021)**
  - *Initially* indicated copay accumulator state ban conflicted with HSA w/HDHP
    - If receive copay assistance would make them ineligible to contribute to an HSA
  - *Revised* to indicate copay accumulator ban conflict only until minimum deductible met ($1,400 individual; $2,800 family)
(C) If under federal law, application of subsection (A) would result in Health Savings Account ineligibility under section 223 of the federal Internal Revenue Code, this requirement shall apply only, for Health Savings Account-qualified High Deductible Health Plans with respect to the deductible of such a plan after the enrollee has satisfied the minimum deductible under section 223, except for with respect to items or services that are preventive care....
Allow Beneficiary to Choose

Choose to contribute to their HSA AND **not apply copay assistance and other support** towards their deductible and out-of-pocket costs until their minimum is met.

OR

Choose to apply copay assistance and other support towards their deductible and out-of-pocket costs AND **not contribute to an HSA**.
Recent State Actions

- **Oklahoma Bulletin (2021)**
  - When enrollee in HDHP & HSA receives credit from 3rd party and/or financial assistance before meeting deductible, individual ineligible to contribute to HSA

- **Kentucky Bulletin (2021)**
  - State ban does not apply until deductible met in HDHPs with HSA

- **Louisiana Bulletin (2022)**
  - Encourages all beneficiaries that participate in HSA plans not to use copay assistance

- **Overly expansive & endangers patient affordability and access to Rx**
Conclusion

- Until Improved Insurance Benefit Design, Patients Must Rely on Copay Assistance to Afford their Rx

- Copay Accumulators Increase Patient Cost-sharing & States Moving to Ban Them

- Any Perceived Conflict w/IRS Laws relative to HSA’s linked to HDHP can be mitigated & Must Not Be Used as a Reason to Ban Copay Assistance
Thank you!

Carl Schmid
Executive Director
HIV + Hepatitis Policy Institute
cschmid@hivhep.org

Follow: @HIVHep
ABA HSA Council* Presentation
NAIC Regulatory Framework Task Force
Wednesday, March 23, 2022

Discussion on the Health Savings Account (HSA), High-Deductible Health Plan (HDHP), and Prescription Drug Copayment Accumulator Issue

Jeff Klein, McIntyre & Lemon, PLLC
Roy Ramthun, President, HSA Consulting Services, LLC

(*) The American Bankers Association’s Health Savings Account Council represents 95% of HSA owners in the United States.
HSAs & HSA-Qualified Plans

• Health Savings Accounts (HSAs) are trust/custodial bank accounts similar to Individual Retirement Accounts
• Adults may contribute to an HSA only if they are enrolled in an “HSA-qualified plan” and do not have other coverage that disqualifies them*
• “HSA-qualified plans” must apply:
  – a minimum deductible to all covered benefits (medical + pharmacy) that are not “preventive care” under IRS rules (which generally follow the ACA definition)
  – an annual limit on out-of-pocket expenses (including all cost-sharing for covered benefits)

*Includes most “lower deductible” plans and Medicare, but also employer-sponsored programs like health flexible spending accounts (FSAs) and health reimbursement accounts (HRAs)
HSA-Qualified Plans

• Minimum annual deductible for HSA-qualified plans (2022)*
  – Self-only coverage - $1,400
  – Family coverage - $2,800

• Annual limits on out-of-pocket expenses cannot exceed (2022)*
  – Self-only coverage - $7,050
  – Family coverage - $14,100

NOTE: ACA borrowed concepts of first-dollar coverage of preventive care and annual limits on out-of-pocket expenses from HSA-qualified plans
  – But ACA OOP limits are now almost 25% higher ($8,700 / $17,400 for 2022) and growing

*Adjusted annually for inflation
Health Savings Accounts

• Contribution limits for eligible adults are based on their coverage and age
  – Self-only coverage - $3,650* (2022)
  – Family coverage - $7,300* (2022)
  – Age 55+ - $1,000 “catch-up” contribution (annually)
• Contributions are tax-deductible from income and/or “pre-tax” when made by
  an employer or via payroll deduction by employees
• Deposits never expire, accumulate annually, and may be invested like IRAs
• HSA funds may be used tax-free for IRS-approved health expenses
• HSA funds belong to the account owner; accounts are completely portable

*Adjusted annually for inflation
Defining the Problem

- **The Problem**: State health insurance mandates can conflict with Federal requirements for HSA-qualified plans.

- **Effect on consumers**: HSA owners lose access to their desired health insurance plan and the financial benefit from contributing to their HSAs.

- **Current example**: “Copay accumulator” laws, some of which don’t coordinate with federal HSA rules.

- **Implication**: Millions of HSA owners could be forced to withdraw mistaken contributions to their HSA and re-file tax returns.
For Consideration

• NAIC, DOIs can have an impact.

• What can DOIs do before HSA-qualified plans are sold?

• You may have health plans in your state marketed as HSA-qualified plans that are not, or would not be, qualified.
  – This increases confusion and raises consumer disclosure and protection issues.
Potential Solutions

• Recommendations:
  – Encourage regulators and legislators to be aware of federal rules for HSAs and HSA-qualified plans.
  – Identify available regulatory authority with respect to mediating between state law and federal law/regulation.
  – Issue a bulletin if appropriate to educate consumers, insurers and financial institutions.

• HSA-qualified plans are in a position similar to private flood insurance.
Benefit Mandates

• Benefit Mandates/Limits on Cost-Sharing

– Bills that seek to protect consumers from out-of-pocket health care costs under their state-regulated insurance coverage sometimes inadvertently threaten HSAs.

– Requiring policies to cover specific benefits without any cost-sharing can be problematic for HSAs because IRS rules only allow zero cost-sharing for “preventive care” services (as defined by the IRS)
Copay Accumulators

• Copay accumulator “adjustment” or “assistance” bills are relatively new. They change existing state law by requiring health plans to count drug coupons and certain third-party payments toward enrollees’ deductibles.

• IRS rules for HSA-qualified plans prohibit counting drug coupons and other third-party payments toward an enrollee’s deductible.

• These bills are well-intended to help patients pay for expensive prescription drugs but have the unintended consequence, due to IRS requirements, of prohibiting individuals and their employers from making future contributions to their HSAs.
Task Force’s Study of the Issue

• Discussion of the IRS position was a major impetus of Colorado Commissioner Conway’s (and former Chair here) agreeing that the Task Force study the issue.

• The IRS wrote a detailed response to the Illinois Department of Insurance dated April 16, 2021 (copy included in Task Force materials) warning of the consequences of these bills and their impact on HSA efficacy.
Summary of IRS Letter

- The IRS did not say patients could not use drug manufacturer coupons.
- The IRS did say that HSA-qualified plans must only count the amount an enrollee pays out-of-pocket for a prescribed drug toward satisfying their deductible without including the value of any drug copay coupon.
  - Example: An individual is prescribed a drug that costs $1,000, but a discount from the drug manufacturer reduces the cost to the individual to $600. Under IRS rules, an HSA-qualified plan may only credit $600 toward the individual’s deductible -- not $1,000. The IRS said, “This same principle also applies to a third-party payment, such as a rebate or coupon, that has the same effect as a discount.”

- We respectfully disagree with those contending the IRS letter is not formal guidance, or that it is open to other interpretation, as it accurately states the law.
Summary of IRS Letter

• The IRS also reiterated that IRS guidance – and not state law – determines whether a given benefit is “preventive care” and, thereby, permissible coverage without a deductible.

• Many state benefit mandate bills go well beyond even US Preventive Services Task Force recommendations.
What’s Happening?

- States that have already adopted unfavorable copay accumulator “adjustment” or “assistance” laws include:

Efforts at Reform

• Our efforts at reform:
  – NCOIL Accumulator Adjust Program Model Act (and we worked with PhRMA in that regard) in November 2021; provides a carve-out for HSA-qualified plans, with a reference to IRC Section 223.
  – Discussions with NAIC leadership, senior NAIC staff, and many of you. This includes state governments and NCOIL.
  – Pending bills with favorable NCOIL or other carve-out language: Connecticut (SB 357), Illinois (HB 4433), Iowa (HF526 & HF 464), Kentucky (SB 134/HB 317), Louisiana (HB 504/SB 366) Maine (LD 1783), Nebraska (LB 718), Oklahoma (HB 4279, HB 3495), Utah (HB 31), South Carolina (H 4987), Virginia (HB 1081/SB 433), Washington (SB 5610). Utah, Virginia and Washington bills have gone to their Governors.
What Should Happen?

• Relief Requested for HSA Owners
  
  – Good: Continued consumer education from DOIs on this subject.
  
  – Better: Collaboration with legislators to ensure state laws permit health plans to meet the IRS requirements for “HSA-qualified plans.”
  
  – Best: A **Model Bulletin or Law** that provides a safe harbor for HSAs.
HSA Penetration in the United States

Estimated People Covered by an HSA by State

<table>
<thead>
<tr>
<th>State</th>
<th>Est. People Covered by an HSA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vermont</td>
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</tr>
<tr>
<td>New Hampshire</td>
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<tr>
<td>Massachusetts</td>
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<tr>
<td>Connecticut</td>
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<tr>
<td>Rhode Island</td>
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</tr>
<tr>
<td>DC</td>
<td>0.15M</td>
</tr>
</tbody>
</table>

Contact Information:

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Jennifer Hatten – Vice President
Roy Ramthun – President, HSA Consulting Services, LLC
Jeff Klein and Chrys Lemon – McIntyre & Lemon, PLLC

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• Chrys Lemon – cdl@mcintyrelf.com
• Jeff Klein – jklein@mcintyrelf.com
March 24, 2020

Charles P. Rettig, Commissioner  
Internal Revenue Service  
1111 Constitution Ave, NW  
Washington, D.C. 20224

Re:  State Actions Relating to Copay Accumulators and Breast Cancer Screening That Affect Eligibility for Health Savings Accounts

Dear Commissioner Rettig,

I write to you as the chief insurance regulator for the State of Illinois. I would like to request your assistance in preserving the eligibility of much of our state’s insured population to contribute to health savings accounts (HSA) under high deductible health plans (HDHP), as well as avoiding tax penalties for individuals who have been relying in good faith on their eligibility in 2020. Illinois has been mindful of placing exemptions for HDHPs in its legislative enactments that prohibit or limit cost-sharing for health care services that are not preventive care, especially since your agency released I.R.S. Notice 2018-121 relating to voluntary male sterilization and contraception.2

Last year, however, Illinois enacted two pieces of legislation that provided important consumer protections to reduce cost-sharing burdens in commercial health insurance coverage: 1) a prohibition on cost-sharing for certain mammograms, MRIs, and comprehensive breast ultrasound screenings, and 2) a copay accumulator ban. Inadvertently, those bills may have incompletely exempted HDHPs or altogether omitted an HDHP exemption that otherwise might have been appropriate.

Although not within my jurisdiction, I should note that the employee group health plans of the State, counties, municipalities, and school districts, as well as our Medicaid plans, are directly or indirectly subject to one or both of these laws affecting cost-sharing. For some of these health plans, the bills explicitly added the cost-sharing restrictions to their respective governing statutes, while in other instances the health plans’ governing statutes already had contained an incorporation by reference of the statutes that the bills were directly amending.

2 See 215 Ill. Comp. Stat. 5/356g(a) and 125/4-6.1(a) (exemption for diagnostic mammograms); 215 Ill. Comp. Stat. 5/356z.4(a)(4) (exemption for voluntary male sterilization procedures); 215 Ill. Comp. Stat. 5/356z.33 (exemption for whole body skin examinations).
Mammograms, MRIs, and Comprehensive Ultrasounds

For years, Illinois has mandated coverage of health care services designed to screen for the presence of occult breast cancer. Currently, under section 356g(a) of the Illinois Insurance Code and Section 4-6.1(a) of the Health Maintenance Organization Act, individual and group policies of accident and health insurance and HMO contracts must cover mammograms, MRIs, and comprehensive ultrasound screenings under specified circumstances, which are identical for each statute.

On August 26, 2019, Illinois enacted Public Act 101-0580, which amended those statutes and included a prohibition on cost-sharing for all these services. The bill exempted diagnostic mammograms from the cost-sharing prohibition “to the extent such coverage would disqualify a high-deductible health plan from eligibility for a health savings account pursuant to Section 223 of the Internal Revenue Code (26 U.S.C. 223).” The cost-sharing prohibition and the HDHP exemption became simultaneously effective for all policies amended, delivered, issued, or renewed on or after January 1, 2020.

Pursuant to section 223 of the Internal Revenue Code (Code), an individual must be enrolled in an HDHP to be eligible to contribute to an HSA. To qualify as an HDHP, a health plan must have an annual deductible satisfying a statutory minimum amount established pursuant to section 223, which the covered individual generally must meet before any benefit is covered in that plan year. Section 223 does not disqualify a health plan from HDHP status solely because it provides benefits for preventive care without a deductible or provides preventive care benefits with a deductible below the minimum for an HDHP. “Preventive care” means preventive care within the meaning of section 1861 of the Social Security Act except as otherwise provided by the Secretary of the United States Treasury.

Although Illinois’ Public Act 101-0580 included an HDHP exemption for diagnostic mammograms, the exemption did not apply to any other health care service within the scope of the twin Illinois statutes. I am concerned about the possibility that some of the other mandated health care services subject to the cost-sharing prohibition might not be “preventive care” under section 223 of the Code. For example, in section 1861 of the Social Security Act and in various guidance documents issued by the Internal Revenue Service (IRS), I have not found any specific mention that preventive care includes a comprehensive ultrasound screening and MRI of an entire breast or breasts.

Additionally, although IRS guidance affirms that any item that is a preventive service under section 2713 of the Public Health Service Act will be treated as preventive care under section 223 of the Code, and although those preventive services include mammograms every 1-2 years for women beginning at age 40, the Illinois statutes also require coverage for a baseline mammogram between ages 35-39, other medically necessary mammograms for women under age 40 with certain risk factors, and medically necessary screening MRIs. These services do not appear to be within the scope of preventive services under section 2713 of the Public Health Service Act. Well before the Patient Protection and Affordable Care Act was enacted, the IRS had released Notice 2004-23, which stated in general terms that screening

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3 215 Ill. Comp. Stat. 5/356g(a).
8 215 Ill. Comp. Stat. 5/356g(a)(1), (3), and (5); 215 Ill. Comp. Stat. 125/4-6.1(a)(1), (3), and (5).
for “Breast Cancer (e.g., Mammogram)” fell within the section 223 safe harbor for preventive care.9 It is unclear whether all of the Illinois-mandated breast cancer screening services fall within the safe harbor described in I.R.S. Notice 2004-23, or whether section 2713 of the Public Health Service Act is supposed to be interpreted to define the exact scope of the safe harbor identified in that Notice.

If any of these breast cancer screening services is not preventive care, then commercial health insurance coverage in Illinois that has been amended, delivered, issued, or renewed since January 1, 2020 may not qualify as an HDHP. However, the scope of the breast cancer screening services required by Illinois law would only be marginally larger than the scope of the services recognized as preventive care under section 223 of the Code. Even comparatively sophisticated insurance purchasers might not realize that their new policy does not meet the criteria, or that their renewed policy has fallen out of compliance with IRS standards. Accordingly, employers and individual insureds would continue contributing to their HSAs based on a good-faith belief in their eligibility. Consumers also might have chosen one plan over another specifically because it looked like an HDHP that would qualify them to contribute to an HSA. Unless your agency deems that all of the Illinois-mandated breast cancer screening services in 215 Ill. Comp. Stat. 5/356g(a) and 215 Ill. Comp. Stat. 125/4-6.1(a) fall within the preventive care safe harbor, I am concerned that, without some form of administrative relief, the beneficiaries of those HSAs could be subject to federal tax penalties despite their reasonable and sincere efforts to comply with the Code’s requirements.

Copay Accumulator Ban

Illinois enacted a copay accumulator ban on August 23, 2019 under Public Act 101-0452. This law requires that, effective January 1, 2020, if any third-party payments, financial assistance, discount, product vouchers, or any other reduction in out-of-pocket expenses is made by or on behalf of a covered individual for prescription drugs, the health insurance issuer must count the amount of that discount or assistance toward the covered individual’s cost-sharing responsibility. The law includes no exemption for HDHPs. Based on my department’s recent conversations with stakeholders in that legislation, no one seemed to be aware while the bill was being drafted that it might affect individuals’ eligibility for HSAs.

When Illinois’ bill was proposed and enacted, other state and federal authorities were undertaking similar measures to allow consumers to make the most of their discounts and third-party assistance. Three other states had recently enacted copay accumulator bans to a greater or lesser degree than Illinois.10 Their bills did not specifically provide an HDHP exemption, though it is possible that their laws already had a general HDHP exemption that could be applied to the copay accumulator ban. Additionally, in April 2019, the U.S. Department of Health and Human Services (HHS) issued its Notice of Benefit and Payment Parameters (NBPP) for 2020.11 In the preamble to the rulemaking, HHS described its rule at 45 C.F.R. § 156.130(h)(1) in a way lending itself to the interpretation that, under limited circumstances, direct support from drug manufacturers for covered individuals’ cost-sharing must be counted toward the annual limitation on cost sharing.12 The agency also indicated that states could require other direct support to be counted toward cost sharing limitations.13 No mention was made of any possible impact on HDHPs.

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12 Id. at 17545.
13 Id. at 17546.
Three days after Public Act 101-0452 was enacted, joint guidance (FAQ-40) was issued by HHS, the U.S. Treasury, and the U.S. Department of Labor.14 In response to the above interpretation of HHS’ April 2019 rulemaking, FAQ-40 observed:

Specifically, Q&A-9 of IRS Notice 2004-50 states that the provision of drug discounts will not disqualify an individual from being an eligible individual if the individual is responsible for paying the costs of any drugs (taking into account the discount) until the deductible of the HDHP is satisfied. Thus, Q&A-9 of Notice 2004-50, requires an HDHP to disregard drug discounts and other manufacturers’ and providers’ discounts in determining if the minimum deductible for an HDHP has been satisfied and only allows amounts actually paid by the individual to be taken into account for that purpose. Such a requirement could put the issuer or sponsor of an HDHP in the position of complying with either the requirement under the 2020 NBPP Final Rule for limits on cost sharing in the case of a drug manufacturer coupon for a brand name drug with no available or medically appropriate generic equivalent or the IRS rules for minimum deductibles for HDHPs, but potentially being unable to comply with both rules simultaneously.

Because of the joint authorship, this information appears to be an interpretation by the U.S. Treasury that section 223 of the Code does not allow a health plan to qualify as an HDHP if the plan counts manufacturers’ and providers’ discounts toward its deductible. Although not specifically addressed, this interpretation could apply to other forms of third-party assistance for covered individuals, as well.

Last month, HHS issued a proposed NBPP for 2021.15 In that document, HHS repeated the above sentences from FAQ-40 verbatim.16 Citing that interpretation, HHS proposed to revise 45 C.F.R. § 156.130(h) in its entirety so that, to the extent consistent with state law, group health plans and health insurance issuers would be permitted, but not required, to count drug manufacturers’ direct support to enrollees toward the annual limitation on cost-sharing.17 Granted, section 223 of the Code does not fall within HHS’ jurisdiction, so their interpretation is not independently authoritative. Nevertheless, HHS’ verbatim repetition of the FAQ-40 guidance and its proposed rule changes in deference to FAQ-40 suggest that the U.S. Treasury has not altered its position that a health plan is not an HDHP if it counts direct manufacturer and provider support for covered individuals toward their deductible.

If that is the case, then commercial health insurance coverage issued or renewed in Illinois on or after January 1, 2020 may not qualify as an HDHP. As with the breast cancer screening situation, even comparatively sophisticated insurance purchasers might not realize that their new policy does not meet IRS criteria for an HDHP, or that their renewed policy has fallen out of compliance with those criteria because it newly complies with Illinois’ copay accumulator ban. Accordingly, employers and individual insureds would continue contributing to their HSAs based on a good-faith belief in their eligibility. Consumers also might have chosen one plan over another specifically because it looked like an HDHP that would qualify them to contribute to an HSA. Unless your agency clearly articulates a position contrary to the one expressed in FAQ-40, I am concerned that, without some form of administrative

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16 Id. at 7135.
17 Id. at 7136.
relief, the beneficiaries of those HSAs could be subject to federal tax penalties despite their reasonable and sincere efforts to comply with the Code’s requirements.

**Relief Requested**

To address these potential consumer problems, I respectfully ask that the IRS issue written guidance clarifying its position and offering relief for our taxpayers, who have reasonably believed in good faith that they have coverage under genuine HDHPs. In particular, I ask that your agency clarify the scope of breast cancer screenings deemed to be “preventive care” under section 223 of the Code, as well as whether there are any circumstances under which a health plan may qualify as an HDHP even if it counts any discounts or third-party financial assistance toward their deductible.

For breast cancer screenings, I am particularly concerned with whether any of the services mandated under 215 Ill. Comp. Stat. 5/356g(a) and 215 Ill. Comp. Stat. 125/4-6.1(a) fall outside the scope of preventive care.

For copay accumulator bans, please note that my department does not believe that counting discounts or financial assistance for preventive care toward a deductible disqualifies a plan from being an HDHP because section 223 of the Code already allows preventive care to be covered without a deductible. Additionally, we do not believe that counting discounts or financial assistance for any care, preventive or not, toward a plan’s cost-sharing requirements is disqualifying with respect to any cost-sharing after the deductible has been reached. Section 223 of the Code requires an HDHP to have a deductible exceeding a certain amount and to have an out-of-pocket maximum no greater than another amount. Counting the covered individual’s discounts and financial assistance toward an out-of-pocket maximum does not appear to conflict with that requirement, as the amount actually paid by the covered individual would still be less than the statutory maximum. If we are in error on either of these points, we would appreciate clarification.

If your guidance indicates that health plans complying with laws such as Public Act 101-0580 or Public Act 101-0452 may not qualify as HDHPs, I respectfully ask that your agency afford a period of transition relief for Illinois, and other states as applicable, to amend its laws with the necessary exemptions. The IRS previously provided such relief when states had enacted a cost-sharing prohibition for contraceptives that did not exempt HDHPs with respect to voluntary male sterilization and contraception.18

My department has been working with state legislators on an exemption bill designed to create a blanket process for HDHP exemptions to Illinois laws that otherwise would preclude HDHP status. The bill was introduced in the Illinois General Assembly last month.19 Particularly because of the strong consumer interests and competing business interests for and against copay accumulators, and because that topic can be a little complicated to explain in conjunction with federal tax laws to persons who do not have the relevant technical background, our bill could require sustained engagement in order to get passed. Furthermore, other states that have enacted copay accumulator bans or that have pending bills containing such bans may decide that they need to undertake their own amendment processes if you issue guidance. On top of that, it is conceivable that the current COVID-19 situation will generally interfere with legislative activities and cause a temporary delay on all but the most essential legislation.

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18 See n.1, supra.
If Illinois or other affected states do not pass an HDHP exemption before the 2021 qualified health plans (QHP) are finalized, those 2021 QHPs may not be able to be brought in line with HDHP requirements. As such, I hope that you will consider offering transition relief through the end of 2021. That timeframe would be consistent with the transition relief previously provided under I.R.S. Notice 2018-12.

I greatly appreciate your attention to this matter and to my request. Please do not hesitate to contact me if you need further information for your deliberation.

Sincerely,

[Signature]

Robert H. Muriel
Illinois Director of Insurance

LETTER SENT ELECTRONICALLY
April 16, 2021

Dana Popish Severinghaus
Acting Director
Illinois Department of Insurance
122 S. Michigan Avenue, 19th Floor
Chicago, IL 60603

Attention: KC Stralka

Dear Ms. Popish Severinghaus:

I am responding to your inquiry dated March 8, 2021, about the interaction of copay accumulator rules and the ability of a health plan to qualify as a high deductible health plan (HDHP) that permits an individual to contribute to a health savings account (HSA). You also asked about the benefits that may be provided by an HDHP before the minimum annual deductible is satisfied.

Section 223 of the Internal Revenue Code allows eligible individuals to deduct contributions to HSAs. Among the requirements for an individual to qualify as an eligible individual under Section 223(c)(1), an individual must be covered by an HDHP and have no disqualifying health coverage. Under Section 223(c)(2), an HDHP is a health plan that satisfies certain requirements, including requirements related to minimum deductibles and maximum out-of-pocket expenses.

Generally, under Section 223(c)(2)(A), an HDHP may not provide benefits for any year until the minimum deductible for that year is satisfied. However, Section 223(c)(2)(C) provides that “[a] plan shall not fail to be treated as a high deductible health plan by reason of failing to have a deductible for preventive care (within the meaning of section 1861 of the Social Security Act, except as otherwise provided by the Secretary).” Therefore, an HDHP may provide benefits defined as preventive care for purposes of Section 223 without a deductible, or with a deductible below the minimum annual deductible otherwise required by Section 223(c)(2)(A).

The issue raised by your inquiry is what amounts count toward the minimum annual deductible for an HDHP. Notice 2004-50, 2004-33 I.R.B. 196, Q&A-9, provides that an individual covered by an HDHP who also has a discount card for health care services or products, may still contribute to an HSA provided that the individual is required to pay the costs of the covered health care until the minimum annual deductible for the HDHP is satisfied. In other words, the minimum annual deductible may only be satisfied by actual medical expenses the covered individual incurred. For example, if a covered
individual is prescribed a drug that costs $1,000, but a discount from the drug manufacturer reduces the cost to the individual to $600, the amount that may be credited towards satisfying the deductible is $600, not $1,000. This same principle also applies to a third-party payment, such as a rebate or coupon, that has the same effect as a discount.

As noted above, an HDHP may provide benefits defined as preventive care for purposes of Section 223 without a deductible, or with a deductible below the minimum annual deductible otherwise required by Section 223(c)(2)(A). A state statute requiring a plan to provide benefits other than preventive care before the minimum annual deductible is satisfied does not change this outcome. Notice 2004-23, 2004-15 I.R.B. 725, explains that state law requirements do not determine if health care is preventive care under Section 223(c)(2)(C). For example, Notice 2018-12, 2018-12 I.R.B. 441, clarifies that male contraception and sterilization services are not preventive care for purposes of Section 223(c). Therefore, a health plan that provides benefits for these services without a deductible or with a deductible below the minimum annual deductible for an HDHP is not an HDHP, even if coverage is required by state statute.

I hope this information is helpful. If you have additional questions, please contact me or Kari DiCecco at 202-317-5500.

Sincerely,

Denise Trujillo
Branch Chief, Health and Welfare
Office of Associate Chief Counsel
(Employee Benefits, Exempt Organizations, and Employment Taxes)
March 22, 2022

Commissioner Vicki Schmidt
Regulatory Framework (B) Task Force, Chair
National Association of Insurance Commissioners
444 North Capitol Street NW, Suite 700
Washington, DC 20001-1512
Forwarded via email: Jolie H. Matthews

RE: AHIP Comments on Coupons, Accumulators, and their impact on HSAs

Dear Commissioner Schmidt,

During the Regulatory Framework (B) Task Force call on March 23, members will be briefed on prescription drug coupon accumulators and separately, how those policies have raised questions relative to Health Saving Accounts (HSAs). AHIP has been deeply engaged with state policymakers across the country on both issues and we appreciate the opportunity to submit comments on these two critically important issues that impact many health care consumers and purchasers.

**COUPONS INCREASE COSTS FOR EVERYONE FOR DRUG MANUFACTURERS’ OWN FINANCIAL GAIN**

Everyone should be able to get the medications they need at a cost they can afford. But drug prices are out of control, and hardworking families feel the consequences every day. Pharmacy costs now represent over 21 cents out of every dollar of premium spent on health care.¹

Drug manufacturers acknowledge their drugs are unaffordable for patients, but rather than choose to lower their prices, they point to their patient assistance programs which offer copay coupons.² Coupons intentionally offset short term cost-sharing for a few patients, while increasing the cost of pharmacy care for everyone, to the financial benefit of drug manufacturers. Coupons encourage the use of high-priced branded prescription drugs when more affordable generic alternatives are available.

Coupons are offered only to a narrow set of patients, for a narrow selection of drugs, and often only for a limited time. Once the patient hits their deductible, drugmakers discontinue the patient’s coupons. This scheme allows drugmakers to keep their underlying prices hidden from patients while keeping their costs extremely high for employers and consumers who end up paying much more in premiums and cost-sharing. This is a vicious cycle as coupons perpetuate higher prices and higher cost sharing and as Pharma pushes for no restrictions on their coupons, more consumers need them.

**Federal Government Labels Coupons as Illegal Kickbacks:** The federal government considers copay coupons illegal kickbacks in Medicare and Medicaid because coupons induce a patient to use a specific drug.³ Since the commercial market is the only market where drug manufacturers may offer copay coupons, Pharma is aggressively seeking policy proposals to protect these promotions and codify their financial gains.

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¹ AHIP; *Where Does Your Health Care Dollar Go?* November 12, 2020.
² Here, the term “copay coupons” is used to represent all payments provided by a third party towards a patient’s cost sharing (copay, coinsurance, deductible). This includes coupons directly from drug manufacturers, but also third-party payments and discount programs from patient assistance programs.
Studies Prove Drug Promotions Are Used to Increase Sales, Fueling Increased Spending Overall:
Repeated studies have shown coupons benefit Big Pharma, instead of the patients they claim to be helping:

- The U.S. House Oversight Committee’s report on drug pricing found that Pharma uses patient assistance programs as a sales tool – focusing on their rates of return, encouraging patients to stay on branded drugs after a generic is introduced, and subsidizing third-party foundations to drive sales and attract patients who otherwise might not have used the high-priced drug.  

  The Committee stressed these programs “do not provide sustainable support for patients and do not address the burden that the company’s pricing practices have placed on the U.S. health care system.”

- A study by Harvard, Kellogg and UCLA economists found drugs with coupons had a higher annual price growth (12-13%) than drugs without coupons (7-8%). And after a generic alternative entered the market, coupons increased spending on branded drugs by $30-$120 million per drug over 5 years.

- The Congressional Research Service released a report which found “Manufacturers may use coupons as part of a marketing strategy to keep prices for brand-name drugs higher than they otherwise would be after a lower-cost generic substitute comes to market.”

- An investigation by the U.S. House Oversight Committee on drugmaker Novartis found the manufacturer projected a potential rate of return of $8.90 for every $1 spent on their copay assistance program for one cancer treatment due to reduced patient price sensitivity, and “[b]ecause oncologic drugs are a necessity for patients, there is less sensitivity to price increases.”

Studies Estimate that Eliminating Coupons Would Save $1 Billion Per Year: A National Bureau of Economic Research (NBER) working paper estimated “…coupons raise negotiated prices of multiple sclerosis drugs by 8% and results in just under $1 billion in increased U.S. spending annually. Combined, the results suggest copayment coupons increase spending on couponed drugs without bioequivalent generics by up to 30 percent.”

Axios reported on the story and wrote: “The study adds further evidence to the idea that drug copay cards are a great short-term deal for patients – and especially the pharmaceutical companies that promote them – but a bad long-term deal for society.”

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4 U.S. Federal House Committee on Oversight and Reform; Drug Pricing Investigation, Majority Staff Report. December 10, 2021.
7 U.S. Federal House Committee on Oversight and Reform; Drug Pricing Investigation: Novartis-Gleevec. Staff Report. October 2020.
Additionally, this parallels a proposal from a group of health care economists, which found if drug copay coupons were eliminated for drugs with a generic alternatives “an estimate total savings to be $1.155 billion per year.”

*Accumulator Programs Hold Drug Manufacturers Accountable for Their High Prices:* Accumulator programs help restore the balance in the system by allowing patients to use manufacturer coupons to save money at the pharmacy counter, but not counting the amount the drug manufacturer has paid for the drug (through the coupon) towards the patient’s deductible or out-of-pocket maximum.

Employers understand how coupons manipulate the market and are working with health plans to develop programs that attempt to restore transparency and shed light on Pharma’s coupon pricing schemes. Guardrails like these are critically important to ensure transparency and affordability in drug pricing for every American.

- As Reuter reports, both Home Depot and Walmart have utilized coupon accumulator programs as it “keeps workers aware of the rising costs of medicines and more likely to accept cheaper alternatives, where possible.”

Employers and health care payers are not the only purchasers that see value in accumulator programs. The Centers for Medicare and Medicaid Services (CMS) explicitly allows accumulator programs in the Exchange Marketplaces as part of their efforts to protect taxpayer dollars and to combat the high out-of-pocket costs for prescription drugs, recognizing the “market distortion effects related to direct drug manufacturer support amounts when consumers select a higher-cost brand name drug over an equally effective, medically appropriate generic drug.”

Having accurate information about coupons and accumulator programs is imperative for regulators and policymakers to fully evaluate this issue.

- Health insurance providers do not receive any of the funds from assistance programs. The value of a coupon moves from the patient to the pharmacy, and then to the drug manufacturer as payment for the drug.
- Drug manufacturers are discontinuing copay coupons on their own terms, for their own financial gain, and without any advance patient notice.
- As health plans abide to the medical loss ratio (which no other drug supply entity is limited by), when policymakers remove coupon transparency programs, premiums and cost sharing must reflect the elimination of that cost saving tool.

*Coupon Programs Should be Fair and Equitable:* To protect affordability while helping all consumers that need assistance, AHIP believes states should take the following steps:

- Ban coupons for brand-name drugs when patients can choose a less expensive alternative as several states have done and are considering.

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10 Dafney, Ody & Schmitt; *Eliminating Prescription Drug Copay Coupons*, proposal for the 1% Steps for Health Care Reform.
• Allow health insurance providers and our employer partners to use coupon accumulator programs.
• Require coupons to be provided to all patients prescribed the drug for the entire plan year.
• Require drugmakers to warn patients if they are going to discontinue the coupon or third-party payment in a subsequent plan year.
• Require drugmakers providing a promotion or assistance to notify the health plan when their enrollee is receiving these payments, including any associated terms and conditions.
• Require drugmakers to disclose the amount they spend on these promotions and other patient assistance programs.
• Require patient assistance programs to annually report the contributions they receive from entities in the pharmaceutical supply chain.

AHIP hopes through the continued review of this issue, policymakers protect Americans from high drug prices rather than allowing drug manufacturers to insulate themselves from public scrutiny, skirt transparency, and maximize their profits by protecting their out-of-control pricing practices.

➢ **Recommendation:** We encourage the NAIC to include the issue of coupons as part of the high drug cost white paper being drafted by the PBM Regulatory Issues (B) Subgroup as this issue is critically important to premiums for a state’s entire population. The paper should include the studies mentioned above to enlist a better understanding of the market and to offer specific guardrails that protect consumers equally.

**HEALTH SAVINGS ACCOUNTS**

Nearly 180 million Americans have employer-provided health insurance coverage, and 40% of them are covered by a Consumer-Directed Health Plan (CDHP), which combines a high-deductible health plan (HDHP) with a tax advantaged health savings account (HSA). HSAs are popular with insurance enrollees as they allow for policyholders to set aside money on a pre-tax basis to pay for qualified medical expenses.13

Drug manufacturers have aggressively pushed state policymakers and impacted stakeholder groups to support statutory protections for their drug coupon assistance programs. The proliferation of coupons and other patient assistance programs has raised questions about whether and how these third-party payments can count towards a patient’s deductible and the potential tax implications. Increased state activity requiring health insurance providers to count these payments towards enrollees’ cost sharing requirements has exacerbated these concerns.

The IRS original guidance14 on discount cards would not disqualify an individual from being eligible for HSA purposes if the individual is required to pay the costs of their health care (taking into account the discount) until the deductible of the HDHP is satisfied. To gain more insight on coupons and the interaction of a state law banning accumulator programs and the ability of an individual to contribute to an

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13 Background: HSA-eligible HDHPs are restricted in covering care that is not considered preventive before a consumer satisfies their plan’s deductible. In July 2019, the Internal Revenue Service (IRS) issued Notice 2019-45 to expand the list of preventive care benefits to include many items and services used to manage chronic health conditions.

14 IRS Notice 2004-50; Guidance on Health Savings Accounts
HSA, the Illinois Department of Insurance requested clarity from the IRS. The Internal Revenue Service responded on April 2021:

“... the minimum annual deductible may only be satisfied by actual medical expenses the covered individual incurred. For example, if a covered individual is prescribed a drug that costs $1,000, but a discount from the drug manufacturer reduces the cost to the individual to $600, the amount that may be credited towards satisfying the deductible is $600, not $1,000. This same principle also applies to a third-party payment, such as a rebate or coupon, that has the same effect as a discount.”

Considering this guidance, laws that ban coupon accumulators could impact an enrollee’s ability to contribute to their HSA and thus AHIP, the American Bankers Association and other interested stakeholders, have advocated for an exception for HSA-eligible HDHPs. We recently raised this issue with the IRS, Department of Labor, and the Department of Health and Human Services and have requested additional clarification regarding HSA plan implications, including a discussion of the types of cost-sharing assistance which have HSA implications. In addition, we asked for further guidance on whether there is a difference between individual and group health plans when coupons are used, and penalties that may result if coupons are used improperly before the deductible is used.

**Recommendations:**

- The NAIC should raise this issue with the tri-agencies, requesting updated clarifying guidance.
- In addition, insurance commissioners should consider educating legislators about the potential impacts banning coupon accumulators may have on HSA coverage and encourage an exemption or safe harbor language within any proposed legislation that has been initiated in their states.
- In states which have passed laws (AR, AZ, CT, GA, IL, KY, LA, NC, OK, TN, VA, WV), commissioners should support new legislation to exempt HSAs from these laws.

We truly appreciate the opportunity to provide information about coupon accumulator programs and their potential impact on Americans with HSAs and stand ready to work with the NAIC on these very important issues. Please contact me at khathaway@ahip.org or 202.870.4468 with any questions.

Sincerely,

Kris Hathaway
Vice President, State Affairs

America’s Health Insurance Plans (AHIP) is the national association whose members provide health care coverage, services, and solutions to hundreds of millions of Americans every day. We are committed to market-based solutions and public-private partnerships that make health care better and coverage more affordable and accessible for everyone. Visit www.ahip.org to learn how working together, we are Guiding Greater Health.

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15 Department of the Treasury; Letter Number 2021-0014, April 16, 2021.
Discriminatory Copay Policies Undermine Coverage for People with Chronic Illness

COPAY ACCUMULATOR ADJUSTMENT POLICIES IN 2022

JANUARY 2022
Introduction

Patients with rare, complex, or chronic diseases such as HIV and hepatitis C often need high-cost specialty medications to manage their conditions and maintain their health. Over the past decade, insurance companies have increasingly shifted the cost of these specialty medications to patients by raising deductibles and the amounts of copayments or coinsurance that patients must pay when they buy their medications.

As a result, many patients with such diseases – including those with health insurance – must rely on financial assistance from charitable foundations and drug manufacturers. Drug manufacturers’ copay assistance programs play a crucial role in helping patients who rely on expensive medications meet those cost-sharing obligations and afford their medication throughout the year. These programs provide a true financial lifeline for many people living with chronic conditions.

However, insurance companies are increasingly undermining this assistance by not counting the amount of money covered by manufacturer copay assistance programs toward enrollees’ annual deductibles and out-of-pocket limit. Instead, they keep the copay assistance funds used, and make enrollees keep paying. This little-known practice is called “copay accumulator adjustment policies” or “CAAPs.” These policies contribute to insurance company profits while shifting the cost of expensive prescription drugs back to the patients who most rely on them, and the policies have become more common in recent years.

Unfortunately, the federal government has allowed copay accumulator adjustment policies to flourish, despite outcries from patients struggling to afford the prescription drugs they need to get and stay healthy. A rule finalized in the last year of the Trump administration allows health insurance companies to use copay accumulator adjustment policies at their discretion, even where there is no medically appropriate generic drug available. Despite President Biden’s Executive Order directing the Department of Health and Human Services (HHS) to review policies that could pose barriers to health care, HHS has not yet reversed that decision.

Copay accumulator adjustment policies add extra costs for patients who have serious, complex, chronic illnesses, making it harder for these patients to afford the medicines they need. And the ongoing coronavirus pandemic has added yet another economic burden for millions of Americans. Many people still struggle to afford basic necessities like rent, gas, and groceries. Unexpected costs due to copay accumulator adjustment programs only increase this financial strain and jeopardize vulnerable patients’ health at a time when people cannot afford to be sick.
This report examines how widely insurance companies have adopted these policies in the health insurance plans they offered to individuals and families in the health insurance marketplace for 2022. We found that companies continue to adopt these harmful policies, undermining access to essential and life-saving medicines for patients with health insurance.

This report covers:

- Overview of Our Methodology
- Findings
- How Copay Assistance Works with Copay Accumulator Adjustment Policies
- Cost-sharing and Plan Design Pose Barriers to Health Care
- The Impact of Copay Accumulator Adjustment Policies on Patients
- Federal Regulation and Legislation Regarding Copay Accumulator Adjustment Policies
- State Actions to Protect Patients’ Access to Prescriptions
- Conclusion

Overview of Our Methodology

Copay accumulator adjustment policies can have an enormous impact on whether patients with HIV, AIDS, viral hepatitis, or other serious or chronic illnesses can afford their medicines. To find out how common these policies are and how they affect patients’ insurance, The AIDS Institute conducted original research, reviewing individual market health plans across all states and the District of Columbia for 2022.¹ We did not review plans in the 12 states with laws that require insurance companies to count copay assistance toward enrollees’ deductibles and out-of-pocket limits. We examined all available policy documents from all insurers that offered plans in the remaining states, looking for specific language regarding enrollee cost-sharing and copay accumulator policies. When those documents were ambiguous or unavailable, we called customer service lines to speak with insurance plan representatives.

Findings

Our review of health insurance plans offered to individuals and families through the ACA marketplaces for 2022 found that copay accumulator adjustment policies are widespread.

Our Review of health insurance plans offered to individuals and families through the ACA marketplaces for 2022 found that copay accumulator adjustment polices are widespread.
• In **35** states, there is **at least one plan** with a copay accumulator adjustment policy.

• In **eight** states, **every plan** includes a copay accumulator adjustment policy: Alabama, Alaska, Delaware, Idaho, Indiana, Iowa, Montana and South Carolina.

• In **30** states, **at least half** of all plans include a copay accumulator adjustment policy (Alabama, Alaska, California, Colorado, Delaware, Florida, Idaho, Indiana, Iowa, Kansas, Maine, Michigan, Minnesota, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Mexico, Ohio, Oregon, Rhode Island, South Carolina, South Dakota, Texas, Utah, Vermont, Washington, Wisconsin, Wyoming).

• In **five** states, **one-third or fewer** plans have a copay accumulator policy: Massachusetts, Mississippi, New York, North Dakota and Pennsylvania.

• In only **three** states plus the District of Columbia, none of the plans include a copay accumulator adjustment policy: Hawaii, Maryland and New Jersey.

• In **12** states plus Puerto Rico, laws prohibiting copay accumulator policies in plans regulated by the states’ departments of insurance will be in effect for 2022: Arkansas, Arizona, Connecticut, Georgia, Illinois, Kentucky, Louisiana, Oklahoma, North Carolina, Tennessee, West Virginia and Virginia. We did not review these states.

Despite allowing insurance companies to adopt copay accumulator policies, HHS did not require them to make information on these policies clear for patients shopping for coverage. Our research found that this information is difficult to locate and is often written in confusing language. People shopping for coverage may need to call specific insurers to learn about any copay accumulator adjustment policies if the information is not available in plan materials. However, customer service representatives do not always know their company’s policy and cannot always answer accurately. In some cases, our researchers were unable to reach a representative at all, suggesting that people shopping for coverage may have the same problem.

• Overall, **36 plans** in the states we researched did not share information about whether they had a copay accumulator policy in plan materials that were available to people before enrollment. Of those, **16 plans** do have a copay accumulator adjustment policy.

• More plans included information about copay accumulator adjustment policies in their materials for 2022 plans than they did in their materials for 2021.
Percent of Plans in States with Copay Accumulator Policies
How Copay Assistance Works with Copay Accumulator Adjustment Policies

When a patient who uses copay assistance has a health insurance plan with a copay accumulator adjustment policy, they may be confused when they have to pay the full cost of their medicines or their full deductible at the pharmacy counter several months into the plan year. At that point, they have spent their copay assistance and may have to pay their entire deductible (again) before they can get their prescription. Their pharmacy bill could run as high as several thousand dollars. Many patients cannot afford that and walk away empty-handed.

Copay accumulator adjustment policies put patients with chronic conditions in a tough position – forcing them to choose between their health and other financial obligations.

Example 1 is a simplified overview of how copay accumulator adjustment policies work for patients who use copay assistance.

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**Example 1**

- Patient has a $1,000 deductible and $500 in copay assistance.

**Without a Copay Accumulator Adjustment Policy**

The $500 copay assistance will count toward the patient’s deductible.

\[ \$1,000 - \$500 = \$500 \]

The patient has to pay only the remaining $500 to reach their deductible.

**With a Copay Accumulator Adjustment Policy**

The $500 copay assistance will not count toward the patient’s deductible.

\[ \$1,000 - \$0 = \$1,000 \]

The patient has to pay the full $1,000 to reach their deductible.

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Example 2 below provides more detail on how, several months into the plan year, a patient’s deductible has not been reduced by the amount covered by their copay assistance. In Example 2, when the patient goes to the pharmacy in May, their copay assistance would be maxed out, and they would have to pay for the remainder of the drug’s cost. The patient would continue
to pay the full price of the drug each month until they reach their deductible. At that point, they’d have to pay a percentage of the full drug price (as determined by their coinsurance).

The difference between the money an insurer would collect under the two examples will vary depending on the health plan’s design and the plan’s specific deductible, coinsurance or copayment, and annual out-of-pocket limit, as well as the cost of the prescription drug and copay assistance. However, the bottom line is consistent: The insurer makes more money when a copay accumulator adjustment policy is part of the health plan.5

Example 2

- Plan deductible: $4,600
- Annual out-of-pocket maximum: $8,550
- Cost-sharing for specialty tier prescription: 50% after deductible is met
- Monthly medication cost: $1,680
- Copay assistance total: $7,200

### Scenario 1: Plan *Without* a Copay Accumulator Program

<table>
<thead>
<tr>
<th></th>
<th>Jan</th>
<th>Feb</th>
<th>Mar</th>
<th>Apr</th>
<th>May</th>
<th>Jun</th>
<th>Jul</th>
<th>Aug</th>
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<th>Dec</th>
<th>Total</th>
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<td>$0</td>
<td>$1,350</td>
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</tbody>
</table>

**Deductible is met** | **Copay assistance limit is met** | **Out-of-Pocket maximum is met**

### Scenario 2: Plan *With* a Copay Accumulator Program

<table>
<thead>
<tr>
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<th>Feb</th>
<th>Mar</th>
<th>Apr</th>
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<th>Insurer collects</th>
</tr>
</thead>
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<tr>
<td>Copay Assistance</td>
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<td>$840</td>
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<td>$7,960</td>
<td></td>
</tr>
</tbody>
</table>

**Deductible is met** | **Copay assistance limit is met** | **Out-of-Pocket maximum is met**

The insurer makes more money when a copay accumulator adjustment policy is part of the health plan.
Cost-Sharing and Plan Design Pose Barriers to Health Care

Health insurance has become more complicated in recent years, which makes it especially difficult for patients with high medical needs to choose a plan that meets those needs. Even very high-quality plans often include significant cost-shifting to patients who need expensive specialty medications, and the way plans shift those costs is not always clear to patients.

These insurance design issues and cost-sharing structure make it difficult for insured people who need health care to know how their insurance works and to afford the care they need.

Insurance Is (Still) Complicated

Many patients are unfamiliar with basic health insurance terms and concepts, such as the difference between a copayment and coinsurance. And most patients have never heard of copay accumulator adjustment policies. On top of that, insurers often describe these policies using complicated language that is buried deep in insurance plan documents. These factors make it difficult for patients who rely on specialty medications to identify which plans available to them include a copay accumulator adjustment policy, or to shop effectively for a plan that does not include such a policy.

Shifting More of the Burden to Patients

Over time, insurers have changed the structure of health insurance benefits to shift more costs to patients. For example, insurers have raised deductibles, added new prescription drug tiers and increased the use of coinsurance for higher tiers, and instituted “utilization management” measures.

Deductibles

In 2022, the average deductible for the most popular level of health plans that offer mid-range coverage is $5,155, more than double the average deductible of $2,556 in 2015. But many people may be enrolled in plans with even higher deductibles: In 2022, plans with the lowest premiums may have deductibles as high as the annual out-of-pocket limit for the year: $8,700 for an individual in 2022, and $9,100 for an individual in 2023. While most enrollees will never hit an out-of-pocket limit of $9,100, people managing a chronic illness requiring specialty medications may be forced to pay this amount every single year, often in the first few months of the year. Since most Americans do not have an extra $9,100 after they pay their health insurance premium, rent or
mortgage, food, transportation, childcare, and other basic needs, copay assistance is often the only way they can afford the medication they need, even if they have insurance.\textsuperscript{11}

Example 3 shows how deductibles have more than doubled since 2015.

**Example 3**

*Change in the Average Deductible for Individual Market Plans 2015-2022*

![Deductible Change Chart]

Source: The AIDS Institute analysis of CMS public use file data and Kaiser Family Foundation reports

Since most Americans do not have an extra $9,100 after they pay their health insurance premium, rent or mortgage, food, transportation, childcare, and other basic needs, copay assistance is often the only way they can afford the medication they need, even if they have insurance.
Prescription Drug Tiers That Use Coinsurance

More plans now have four or more prescription drug formulary tiers. In 2019, 84% of silver plans in the marketplace (the most popular plans) used a specialty drug tier. Health insurers place many of the drugs used to treat complex diseases such as HIV, hemophilia, arthritis and epilepsy in the highest or specialty tiers. Higher formulary tiers often use coinsurance (a percentage of the drug’s list price) rather than copayments (a fixed dollar amount). And since these tiers have higher cost-sharing, plans with more tiers require patients to pay more out of pocket.

It is very common for insurers to charge coinsurance of 30-50% for higher tiers. One group of researchers found that the vast majority (81%) of silver level individual market plans required enrollees to pay coinsurance for specialty drugs, and just 12% cover any specialty drugs before the deductible is met. The median coinsurance amount for the 69% of silver plans using coinsurance post-deductible was 40%. That 40% could translate to thousands of dollars a month for a patient with a chronic condition. And because coinsurance is based on the list price rather than the discounted price the insurer pays for prescription drugs, patients are paying significantly more of the cost of their medication than the coinsurance percentage might indicate.

Utilization Management

Insurers do not rely just on cost to deter patients from expensive treatments. Insurance plans also employ “utilization management tools,” such as step therapy, generic substitution, prior authorization, and pill quantity limits. These techniques enable the insurer to steer patients toward less expensive therapies whenever possible. Patients who are ultimately prescribed more expensive treatments have exhausted all other options, gaining access to them because less expensive options did not work or were not medically appropriate for them. Copay assistance offers a lifeline to these patients to help them afford the steep cost-sharing charged for these treatments.

The Impact of Copay Accumulator Adjustment Policies on Patients

High Out-of-Pocket Costs Prevent Patients From Taking Their Medications

For many diseases, like HIV and hepatitis C, there are no generic alternatives to brand-name medications. In addition, even when generics
are available, they are still often prohibitively expensive and unaffordable for patients. For example, a generic drug that came on the market in 2018 to treat multiple sclerosis (MS) was priced 20% lower than the brand-name drug – at approximately $60,000 a year.\(^\text{15}\)

High monthly costs make it more likely that patients will stop taking their medications, which could seriously worsen their health over the long term. One survey found that among people who said they did not take their medication as prescribed due to cost, 20% did not fill a prescription, and another 12% skipped doses or cut pills in half to extend their supply.\(^\text{16}\)

Not following a prescribed treatment regimen for a complicated health condition can lead to dangerous health consequences, such as irreversible worsening of their disease, hospitalization or becoming resistant to the drug. Another patient experience survey revealed that of the individuals who experienced an interruption to their prescription drug adherence, 82% of patients with infectious diseases like HIV reported negative health outcomes.\(^\text{17}\)

Even delaying treatment temporarily can have a dramatic impact on a patient’s long-term health and end up costing the health care system more in emergency room visits or additional medical treatment. And during the ongoing coronavirus pandemic, hospitals across the nation have, at times, been unable to ensure that they can provide care for non-COVID patients who need hospitalization.\(^\text{18}\)

How much does a patient have to pay for their medicine before they opt to leave their prescription at the counter? That amount is relatively low. Recent research on medication adherence found that when out-of-pocket costs reach $75-$125, more than 40% of patients leave their prescriptions at the counter. When those costs hit $250, over 70% of patients leave empty-handed.\(^\text{19}\)

Copay assistance ensures that patients with expensive, chronic conditions can afford their medicines even with the growing out-of-pocket costs that insurers require. Copay accumulator adjustment policies remove that safety net.

**Copay Accumulator Adjustment Policies Can Also Harm People with Employer-Sponsored Insurance**

While The AIDS Institute focused on insurers in the individual market because information on their health plan policies is more accessible, copay accumulator adjustment policies are also prevalent in employer-sponsored health plans. Almost half (49.6%) of Americans...
who have health insurance are covered by employer-sponsored health insurance.\textsuperscript{20} Therefore, decisions made by employers about pharmacy benefit design have the potential to affect a much greater number of people.

With employers concerned about rising health care expenditures, they have increasingly turned to cost control mechanisms. A 2019 survey of a sample of large employers found that 34\% were already using copay accumulator adjustment policies, and an additional 4\% sought to add them in the next year – a significant increase over previous years.\textsuperscript{21} The three largest pharmacy benefit managers (PBMs) are now marketing copay accumulator adjustment policies to employers that are designing their insurance plans,\textsuperscript{22} which may be contributing to their increasing prevalence. However, the decision of how to balance reduced costs and employees’ health is ultimately up to employers.

An additional reason to be concerned about copay accumulator adjustment policies in employer-sponsored health insurance plans is that most of the large plans do not have to follow state insurance laws. Therefore, even in states that have banned copay accumulator programs, a significant number of residents may still be enrolled in health insurance plans that have such programs.\textsuperscript{23}

It will take federal regulatory or legislative action to truly protect people from copay accumulator programs.

**Health Insurers Profit from Using Copay Accumulator Adjustment Policies**

One argument that health insurers use to justify copay accumulator adjustment policies is that copay assistance leads patients to use higher-cost drugs, which then drives up drug prices. However, research shows that the use of copay assistance does not affect overall drug prices and does not steer patients toward more expensive drugs.\textsuperscript{24}

Instead, this assistance helps patients afford the medications they’ve been prescribed. Furthermore, copay assistance makes up a tiny sliver of overall pharmaceutical claims. One group of researchers who studied the issue concluded that of all the commercial market\textsuperscript{25} prescription purchases between 2013 and 2017, only 3.4\% were bought using copay assistance, and only 0.4\% of those prescription drugs had a generic equivalent.\textsuperscript{26}

Another factor that affects whether health insurers use copay accumulator programs is that they gain financially by their use. Example 2 on p. 8 shows how payments for a prescription

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drug would work over the course of a plan year for a plan with a copay accumulator adjustment policy and a plan without one. The example shows that when a plan has such a policy, the insurer collects significantly more money for the same medicine than it would without the policy. That additional money comes from the amount covered by the copay assistance even though those funds were intended to go to patients. This can force patients to pay again the amount they received in cost-sharing assistance.

Clearly, insurers have taken advantage of the liberties granted by the federal government through recent regulations to line their pockets at the expense of patients.

Federal Regulation and Legislation Regarding Copay Accumulator Adjustment Policies

The federal government has taken multiple positions on copay accumulator adjustment policies over the past few years in its annual “Notice of Benefit and Payment Parameters,” (NBPP) which governs all private health insurance subject to the Affordable Care Act.27

The 2020 rule significantly restricted the ability of insurers to use copay accumulator adjustment policies except in very limited circumstances, allowing the practice only for specialty drugs that have a medically-appropriate generic equivalent.28 While a broad ban on all copay accumulator adjustment policies would have provided the best patient protection, this final rule was still a significant win for patients and patient advocates.

However, before the rule went into effect, HHS announced that it would delay enforcement until 2021.29 The final 2021 Notice of Benefit and Payment Parameters officially reversed HHS’ original stance on patient copay assistance: The notice permitted insurers to use copay accumulator adjustment policies whenever they want without restrictions.30 Furthermore, the final rule removed the protection for copay assistance in cases where no medically appropriate generic drug is available. This was a devastating blow to patient access and put those who rely on specialty medications in a precarious position.

HHS’ rationale for reversing course on copay accumulator adjustment policies is complicated. It defers to the IRS, which contends that the rule conflicted with an IRS policy prohibiting the use of pharmacy coupons or discounts for people who have a Health Savings Account (HSA) paired with a high-deductible health plan.31 That IRS policy says that people who have an HSA must pay the full amount of their health care without discounts until they meet the
minimum deductible for such a plan ($1,400 for an individual, $2,800 for a family). In order to accommodate the IRS’ concern, HHS opted to remove the restriction on use of copay accumulator adjustment policies altogether, rather than modify it to ensure that copay assistance is counted toward any deductible after the first $1,400 is met for enrollees who contribute to an HSA.

The failure of HHS to regulate insurers’ use of copay accumulator adjustment policies prompted congressional leaders to introduce legislation that requires health plans to count the value of copay assistance toward patient cost-sharing requirements. Representatives Donald McEachin (D-VA) and Rodney Davis (R-IL) introduced bipartisan legislation in November 2021, entitled the “Help Ensure Lower Patient Copays Act,” HR 5801. If enacted, this legislation would prohibit the use of copay accumulator adjustment policies in individual and employer health plans.

State Actions to Protect Patient Access to Prescriptions

While the federal government has not prohibited copay accumulator adjustment policies, HHS’ 2021 Notice of Benefit and Payment Parameters allowed states to do so. The growing number of copay accumulator programs, combined with the lack of federal patient protections, has motivated more states to act. To date, 12 states have adopted laws requiring insurance plans and pharmacy benefit managers (PBMs) to count the value of copay assistance toward an enrollee’s annual deductible and out-of-pocket limit.

- To date, six states and one U.S. territory have enacted laws requiring insurers to count all copayments made by or on behalf of enrollees toward their annual deductibles and out-of-pocket limits: Connecticut, Illinois, Louisiana, Oklahoma, Virginia, West Virginia and Puerto Rico.
- Six more states enacted laws that prohibit copay accumulator adjustment policies for prescription drugs when no generic alternative is available but allow insurers to exclude copay assistance for a brand-name drug when a generic is available: Arizona, Arkansas, Georgia, Kentucky, North Carolina and Tennessee.

As state legislatures look ahead to their 2022 sessions, several states have already begun to build on the work started in prior sessions. And many additional states are prioritizing copay assistance bills. States where patient advocates are building grassroots support and working with key legislators for 2022
include Colorado, Florida, Indiana, Maryland, Mississippi, Ohio, Oregon, Pennsylvania, Rhode Island, South Dakota and Texas.

**Conclusion**

At the most basic level, copay accumulator adjustment policies discriminate against people living with chronic illness, interrupting their access to needed treatment and threatening their health. The federal government and state governments should take action to address this problem and help patients.
Endnotes

1 The individual market is the health insurance market for coverage that is available to people who do not get health coverage through their employer or a government program. It is bought directly from an insurer.

2 States in which at least 66% of insurance plans have copay accumulator policies include Alabama, Colorado, Connecticut, Delaware, Florida, Hawaii, Idaho, Indiana, Iowa, Kentucky, Louisiana, Maine, Massachusetts, Michigan, Minnesota, Missouri, Montana, Nevada, New Hampshire, New Mexico, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, South Carolina, Tennessee, Texas, Washington and Wisconsin.

3 Information on copay accumulator policies was gathered by calling each insurer’s customer service line.

4 BCBS, Alabama; Western Health Advantage, California; Highmark, Delaware; Capital Health Plan, Florida; US Health & Life, Indiana, Kansas, Michigan; BCBS of Kansas; Community Health Options, Maine; Fallon Community Health Plan, Massachusetts; Aetna, Missouri; Health Plus, New York; Geisinger Health Plan, Pennsylvania; Avera, South Dakota; MVP, Vermont; Community Health Network, Washington; WPS, Wisconsin.

5 Prescription Costs, Health Plan Design, and Copay Assistance Tables: These scenarios also do not take into account the discount that the insurer receives through negotiations with the drug’s manufacturer. This discount — in the form of a rebate — adds to the insurer’s net gains, since those savings are not passed on to patients.

%241%2C432%20to%241%2C533.


8 The Affordable Care Act limits the amount that people must pay for health care every year with an “annual out-of-pocket limit.” That limit is $8,700 in 2022 and is scheduled to increase to $9,100 in 2023.


13 Cost-sharing is the portion of costs the enrollee pays out of pocket for insurance, such as deductibles, copayments, or coinsurance. This does not include premiums.

14 K. Hempstead, Marketplace Pulse: Cost-Sharing for Drugs Rises Sharply at Higher Tiers.


20 Kaiser Family Foundation, “Health Insurance Coverage of the Total Population,” 2020, https://www.kff.org/other/state-indicator/total-population/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D.


23 Aimed Alliance, “An Update on Copay Accumulator Policies.”

24 IQVIA, Medicine Use and Spending in the U.S.

25 The commercial market refers to health insurance that is not provided by a government program. It includes employer-sponsored insurance and insurance that people buy through the ACA's health insurance marketplaces.


27 Department of Health and Human Services, “Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2020,” The NBPP is issued every spring, carrying the date of the following calendar year (the 2020 NBPP was issued in April 2019).

28 The Notice of Benefit and Payment Parameters permitted exclusions where a generic equivalent is available and medically appropriate, but it also allowed for an exceptions and appeals process for patients who need the brand-name version of a drug.


32 Note that not all health plans with high deductibles may be paired with an HSA. The IRS defines a high-deductible health plan (HDHP) as a plan that has a deductible of between $1,400 and $7,050 for a plan that covers one person. In the individual market, many plans have deductibles higher than $7,050 and thus cannot be used with an HSA. Although not technically an HDHP by IRS standards, most people consider a plan with a deductible of between $7,050 and $8,700 (the maximum deductible for an ACA-qualified health plan in 2022) to be a high deductible plan.
**Federal Regulation and Legislation Timeline**

<table>
<thead>
<tr>
<th>Timeline</th>
<th>Summary</th>
<th>Policy Vehicle</th>
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</thead>
<tbody>
<tr>
<td>April 2019</td>
<td>The 2020 Notice of Benefit &amp; Payment Parameters (NBPP) finalized in April 2019, included a provision that stated health plans must count manufacturer copay assistance toward the beneficiary's deductible and out-of-pocket costs for a brand drug where no generic equivalent is available. The provision also outlined the requirement to count manufacturer assistance for generic prescriptions through an appeals process.</td>
<td>2020 NBPP</td>
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<td>August 2019</td>
<td>In August 2019, HHS with the Dept of Labor and Treasury Dept issued and FAQ about the ACA Implementation. This announced CCIIO's decision to delay enforcement of the copay accumulator provision of the 2020 NBPP, citing a possible conflict with a 2004 IRS rule related to high deductible health plans.</td>
<td>Tri-Agency FAQ</td>
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<tr>
<td>May 2020</td>
<td>The 2021 NBPP finalized in May 2020 reversed HHS' official policy on copay accumulators, leaving it to the discretion of health plans whether or not to count manufacturer copay assistance toward a beneficiary's cost-sharing responsibilities.</td>
<td>2021 NBPP</td>
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<td>July 2020</td>
<td>Legislation was introduced in July 2020 in the House that would delay the implementation of the 2021 NBPP due to COVID-19.</td>
<td>HR 7647</td>
</tr>
<tr>
<td>November 2021</td>
<td>Legislation introduced in November 2021 by Representatives McEachin and R. Davis that will require copay assistance to be counted toward out-of-pocket cost-sharing requirements, and close a loophole that permits insurers to deem certain drugs “non-essential,” for which no cost sharing paid will count toward the deductible or out-of-pocket maximum.</td>
<td>HR 5801</td>
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## State Legislation Passed

<table>
<thead>
<tr>
<th>State</th>
<th>Copay Accumulator Language</th>
<th>Source / Date Signed into Law</th>
</tr>
</thead>
</table>
| **West Virginia** | When calculating an insured's contribution to any applicable cost sharing requirement, including, but not limited to, the annual limitation on cost sharing subject to 42 U.S.C. §18022(c) and 42 U.S.C. § 300gg-6(b):  
(1) An insurer shall include any cost sharing amounts paid by the insured or on behalf of the insured by another person; and (2) A pharmacy benefits manager shall include any cost sharing amounts paid by the insured or on behalf of the insured by another person. | West Virginia HB2770 3/9/2019 |
| **Virginia** | When calculating an enrollee's overall contribution to any out-of-pocket maximum, deductible, copayment, coinsurance, or other cost-sharing requirement under a health plan, a carrier shall include any amounts paid by the enrollee or paid on behalf of the enrollee by another person.                                                                                                   | Virginia SB1596 3/21/2019    |
| **Arizona** | This law requires that financial assistance from outside parties, including drug manufacturers, count towards an enrollee's total out-of-pocket maximum when there is no generic version of their prescription medication available, or when the patient has received permission to take the name brand drug through prior authorization, step therapy, or an issuer's appeals process. | Arizona HB2166 4/11/2019    |
| **Illinois** | A health care plan shall apply any third-party payments, financial assistance, discount, product vouchers, or any other reduction in out-of-pocket expenses made by or on behalf of such insured for prescription drugs toward a covered individual's deductible, copay, or cost-sharing responsibility, or out-of-pocket maximum associated with the individual's health insurance. | Illinois HB0465 8/23/2019   |
| **Georgia** | When calculating an insured's contribution to any out-of-pocket maximum, deductible, or copayment responsibility, a pharmacy benefits manager shall include any amount paid by the insured or paid on his or her behalf through a third-party payment, financial assistance, discount, or product voucher for a prescription drug that does not have a generic equivalent or that has a generic equivalent but was obtained through prior authorization, a step therapy protocol, or the insurer's exceptions and appeals process. | Georgia SB313 8/5/2020      |
| **Kentucky** | To the extent permitted under federal law, an insurer issuing or renewing a health plan on or after the effective date of this Act, or a pharmacy benefit manager, shall not:  
(a) Require an insured purchasing a prescription drug to pay a cost-sharing amount greater than the amount the insured would pay for the drug if he or she were to purchase the drug without coverage. (already in statute prior to SB 45)  
(b) Exclude any cost-sharing amounts paid by an insured or on behalf of an insured by another person for a prescription drug, including any amount paid under paragraph (a) of this subsection, when calculating an insured's contribution to any applicable cost-sharing requirement. The requirements of this paragraph shall not apply in the case of a prescription drug for which there is a generic alternative, unless the insured has obtained access to the brand prescription drug through prior authorization, a step therapy protocol, or the insurer's exceptions and appeals process. | Kentucky SB45 3/25/2021     |
<table>
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<tr>
<th>State</th>
<th>Act Description</th>
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<td>Oklahoma</td>
<td>Any of the following acts by an insurer, if committed in violation of Section 1250.3 of this title, constitutes an unfair claim settlement practice exclusive of paragraph 16 of this section which shall be applicable solely to health benefit plans: 18. As a health insurer that provides pharmacy benefits or a pharmacy benefits manager that administers pharmacy benefits for a health plan, failing to include any amount paid by an enrollee or on behalf of an enrollee by another person when calculating the enrollee’s total contribution to an out-of-pocket maximum, deductible, copayment, coinsurance or other cost-sharing requirement.</td>
<td>Oklahoma HB2678</td>
<td>4/19/2021</td>
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<tr>
<td>Arkansas</td>
<td>(b)(1) When calculating an enrollee’s contribution to any applicable cost-sharing requirement, a healthcare insurer shall include any cost-sharing amounts paid by the enrollee or on behalf of the enrollee by another person. (2) The cost-sharing requirement under subdivision (b)(1) of this section does not apply for cost-sharing of a prescription drug if a name-brand prescription drug is prescribed and the prescribed drug: (A) Is not considered to be medically necessary by the prescriber; and (B) Has a medically appropriate generic prescription drug equivalent.</td>
<td>Arkansas HB1569</td>
<td>4/27/2021</td>
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<td>Tennessee</td>
<td>(a) When calculating an enrollee’s contribution to an applicable cost sharing requirement, an insurer shall include cost sharing amounts paid by the enrollee or on behalf of the enrollee by another person. (b) Subsection (a) does not apply to a prescription drug for which there is a generic alternative, unless the enrollee has obtained access to the brand name prescription drug through prior authorization, a step therapy protocol, the insurer’s exceptions and appeals process, or as specified in § 53-10-204(a).</td>
<td>Tennessee HB619</td>
<td>5/12/2021</td>
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<tr>
<td>Connecticut</td>
<td>Sec 4) and 5) When calculating an enrollee’s liability for a coinsurance, copayment, deductible or other out-of-pocket expense for a covered benefit, give credit for any discount provided or payment made by a third party for the amount of, or any portion of the amount of, the coinsurance, copayment, deductible or other out-of-pocket expense for the covered benefit.</td>
<td>Connecticut SB1003</td>
<td>6/2/2021</td>
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<td>Louisiana</td>
<td>B. When calculating an enrollee’s contribution to any applicable 30 cost-sharing requirement, a health insurance issuer shall include any cost-sharing amounts paid by the enrollee or on behalf of the enrollee by another person.</td>
<td>Louisiana SB94</td>
<td>6/21/2021</td>
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<td>North Carolina</td>
<td>(c1) When calculating an insured’s contribution to any out-of-pocket maximum, deductible, copayment, coinsurance, or other applicable cost-sharing requirement, the insurer or pharmacy benefits manager shall include any amounts paid by the insured, or on the insured’s behalf, for a prescription that is either: (1) Without an AB-rated generic equivalent. (2) With an AB-rated generic equivalent if the insured has obtained authorization for the drug through any of the following: a. Prior authorization from the insurer or pharmacy benefits manager. b. A step therapy protocol. c. The exception or appeal process of the insurer or pharmacy benefits manager.</td>
<td>North Carolina SB257</td>
<td>9/20/2021</td>
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<td>Puerto Rico</td>
<td>Any health insurance organization or insurer that provides prescription drug benefits, a pharmacy provider or benefits manager shall include in the calculation or requirement of cost sharing or out-of-pocket maximum, any payment, discount, or item that is part of a financial assistance program, discount plan, coupon, or any contribution offered to the insured by the manufacturer. These items shall be considered for the sole benefit of the patient in the calculation of his contribution, out-of-pocket expenses, copayments, co-insurance, deductible or in compliance with shared contribution requirements. These contributions, discounts, coupons will be available and may be used at all health care provider, in accordance with program requirements, regardless of where the discount or coupon is acquired. The use of the benefit accumulator, maximizer, or any other similar program that has the effect of implementing a restriction on liability set forth in this subparagraph is prohibited.</td>
<td>Puerto Rico S.1658</td>
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<td>NCOIL Model Language</td>
<td>When calculating an enrollee’s overall contribution to any out-of-pocket maximum or any cost-sharing requirement under a health plan, a [Carrier/Insurer/Issuer] or pharmacy benefit manager shall include any amounts paid by the enrollee or paid on behalf of the enrollee by another person.</td>
<td>Introduced to NCOIL and under considering in 2021</td>
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## 2022 Copay Accumulator Data Collection Appendix

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*Plan applies copay assistance for brand drug with no generic equivalent to patient’s deductible and out-of-pocket cost.
Acknowledgements

This report was authored by Stephanie Hengst, Manager,Policy and Research, The AIDS Institute

With assistance from:
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Discuss Any Other Matters Brought Before the Task Force
—Commissioner Vicki Schmidt (KS)