

Revised: 11/27/23

2023 Fall National Meeting
Orlando, Florida

REGULATORY FRAMEWORK (B) TASK FORCE

Friday, December 1, 2023

12:00 – 1:00 p.m.

Hilton Orlando Bonnet Creek—Floridian Ballroom J-L & Corridor III—Level 1


ROLL CALL

Sharon P. Clark, Chair	Kentucky	D.J. Bettencourt	New Hampshire
Glen Mulready, Vice Chair	Oklahoma	Justin Zimmerman	New Jersey
Mark Fowler	Alabama	Mike Causey	North Carolina
Lori K. Wing-Heier	Alaska	Jon Godfread	North Dakota
Peni Itula Sapini Teo	American Samoa	Remedio C. Mafnas	Northern Mariana Islands
Ricardo Lara	California	Judith L. French	Ohio
Michael Conway	Colorado	Andrew R. Stolfi	Oregon
Andrew N. Mais	Connecticut	Michael Humphreys	Pennsylvania
Karima M. Woods	District of Columbia	Alexander S. Adams Vega	Puerto Rico
Dean L. Cameron	Idaho	Larry D. Deiter	South Dakota
Amy L. Beard	Indiana	Cassie Brown	Texas
Doug Ommen	Iowa	Jon Pike	Utah
Vicki Schmidt	Kansas	Scott A. White	Virginia
Timothy N. Schott	Maine	Mike Kreidler	Washington
Gary D. Anderson	Massachusetts	Allan L. McVey	West Virginia
Grace Arnold	Minnesota	Nathan Houdek	Wisconsin
Eric Dunning	Nebraska		

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

AGENDA

1. Consider Adoption of its Sept. 29 and Summer National Meeting Minutes Attachment One
—*Commissioner Sharon P. Clark (KY)*
2. Consider Adoption of its Subgroup and Working Group Reports
 - A. Accident and Sickness Insurance Minimum Standards (B) Subgroup
—*Andrew Schallhorn (OK) and Rachel Bowden (TX)*
 - 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)*

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3. Hear a Presentation on the Results and Impact of the Copay Accumulator Adjustment Programs Lawsuit—*Carl Schmid (HIV + Hepatitis Policy Institute)*
 4. Hear a Presentation on “Cost: The Greatest Barrier to Access”
—*Jessica Brooks-Woods (National Association of Benefits and Insurance Professionals (NABIP))*
 5. Discuss Any Other Matters Brought Before the Task Force
—*Commissioner Sharon P. Clark (KY)*
 6. Adjournment

Agenda Item #1

**Consider Adoption of its Sept. 29 and Summer National Meeting Minutes
—*Commissioner Sharon P. Clark (KY)***

Draft: 10/10/23

Regulatory Framework (B) Task Force
Virtual Meeting
September 29, 2023

The Regulatory Framework (B) Task Force met Sept. 29, 2023. The following Task Force members participated: Sharon P. Clark, Chair (KY); Glen Mulready, Vice Chair, represented by Ashley Scott (OK); Lori K. Wing-Heier represented by Sarah Bailey (AK); Mark Fowler represented by Anthony L. Williams (AL); Ricardo Lara represented by Tyler McKinney (CA); Michael Conway represented by Debra Judy (CO); Andrew N. Mais represented by Jared Kosky (CT); Doug Ommen represented by Andria Seip and Brad Biren (IA); Dean L. Cameron represented by Weston Trexler (ID); Amy L. Beard represented by Alex Peck (IN); Vicki Schmidt represented by Julie Holmes (KS); Gary D. Anderson represented by Kevin Beagan and Rebecca Butler (MA); Timothy N. Schott (ME); Mike Causey represented by Jackie Obusek and Ted Hamby (NC); Jon Godfread (ND); Eric Dunning represented by Martin Swanson (NE); D.J. Bettencourt represented by Michelle Heaton (NH); Justin Zimmerman represented by Paul Lupo (NJ); Judith L. French represented by Craig Kalman (OH); Andrew R. Stolfi represented by TK Keen (OR); Michael Humphreys (PA); Larry D. Deiter represented by Jill Kruger (SD); Cassie Brown represented by Rachel Bowden (TX); Jon Pike represented by Shelley Wiseman (UT); Scott A. White represented by Julie Fairbanks and Jackie Myers (VA); Mike Kreidler represented by Ned Gaines (WA); Nathan Houdek represented by Jennifer Stegall (WI); and Allan L. McVey represented by Joylynn Fix, Erin K. Hunter, and Mary Jo Lewis (WV). Also, participating was: Chlora Lindley-Myers (MO).

1. Adopted its 2024 Proposed Charges

Commissioner Clark said that prior to the meeting, NAIC staff circulated the Task Force's 2024 proposed charges. She explained that the 2024 proposed charges revise one of the Mental Health Parity and Addiction Equity Act (MHPAEA) (B) Working Group's charges to better align with its current work. Commissioner Clark also explained that for now, the Task Force proposes retaining the Pharmacy Benefit Manager Regulatory Issues (B) Subgroup's charges from 2023. She said she anticipates that after the white paper *A Guide to Understanding Pharmacy Benefit Manager and Associated Stakeholder Regulation* (PBM white paper) is finalized, the Task Force will consider revised charges for the Subgroup or a successor group early next year after the Task Force is reappointed for 2024. She said the Task Force did not receive any comments on its 2024 proposed charges.

Kruger made a motion, seconded by Gaines, to adopt the Task Force's 2024 proposed charges (Attachment One-A). The motion passed unanimously.

2. Adopted the PBM White Paper

Commissioner Clark said the Task Force's next item of business is to consider adoption of the PBM white paper. She said the Pharmacy Benefit Manager Regulatory Issues (B) Subgroup adopted the PBM white paper on July 27 after almost two years of work. She said the Task Force received comments on the white paper, which were distributed and posted on the Task Force's web page.

Commissioner Clark said that prior to this meeting, NAIC staff distributed a revised draft of the PBM white paper, which included some suggested updates following its July 27 adoption. Jolie H. Matthews (NAIC) said the suggested updates include revisions to the PBM white paper's Introduction section noting the Subgroup's July 27 adoption. She said the suggested updates also add language discussed during the Subgroup's July 27 meeting highlighting the Subgroup's intent that the white paper be considered a snapshot in time and subject to future revision because of the complex issues involved and ongoing and future litigation. Matthews said other suggested

updates revise the Enforcement and Federal Preemption Issues section reflecting the federal 10th Circuit Court of Appeals recent decision in the *Pharmaceutical Care Management Association (PCMA) v. Mulready* case.

Commissioner Clark asked for comments. Commissioner Godfread expressed concerns about the PBM white paper's Recommendation section. He said that given the inclusion of language noting that the PBM white paper is intended to reflect a snapshot in time and the potential continuation of work, the recommendations seem to be more like future charges for the Subgroup or its successor group. He said that because of this, he believes the Recommendation section should be removed and considered separately later as the work moves forward with the current Subgroup or its successor group. Swanson and Kosky expressed support for Commissioner Godfread's comments. Commissioner Godfread made a motion, seconded by Swanson, to remove the Recommendation section. The motion passed.

Commissioner Clark asked for additional comments. Kosky said Connecticut cannot support the PBM white paper's adoption because it believes it is flawed in many respects, particularly its lack of adequate citations and diversity in the sourcing of its language, biased tone in some areas, and inaccuracies. He explained that during the Subgroup's almost two years of work on the white paper, Connecticut noted these objections. He explained that Connecticut voted in favor of the motion to adopt the PBM white paper and move it forward for the Task Force's consideration to keep the process moving forward. He said that given these issues, Connecticut is concerned about whether this is an effective white paper. Kosky said that for Connecticut, when talking about a white paper it should be an authoritative research-based document that presents clear and accurate information and provides expert analysis about a topic. He also noted the lack of information in the PBM white paper concerning employers and consumers. He said the point of the PBM white paper was to try to find solutions to lower the cost of prescription drugs to consumers, and because of this, it should be a factual statement to assist state insurance regulators in making decisions related to the issues discussed. Keen acknowledged Kosky's comments. He said the Subgroup worked through the comments it received and addressed them as best it could due to the wide range of opinions on the issues the white paper discusses. Keen noted that the white paper's focus is on PBM regulation and the role PBMs play in the prescription drug ecosystem.

Commissioner Godfread expressed support for many of Kosky's comments. He noted that North Dakota has fundamental issues with the PBM white paper and the role of state insurance regulators in regulating PBMs. He said because of these concerns and issues, North Dakota will oppose adopting the white paper. Swanson said Nebraska also cannot support the PBM white paper's adoption because of concerns about its tone and some of its conclusions. He also said Nebraska already has a statute related to the issues discussed in the white paper and, as such, it is looking for what is next on these issues. Holmes also said that based on Connecticut's, Nebraska's, and North Dakota's comments, Kansas also would be voting to oppose the PBM white paper's adoption.

Commissioner Humphreys discussed the reason why the Subgroup developed the white paper. He noted that initially the Subgroup was charged with developing an NAIC model regulating PBMs. The proposed NAIC model failed to receive sufficient votes from the Executive (EX) Committee and Plenary for adoption. Following that action, the Subgroup pivoted to developing the PBM white paper for those states interested in looking at what other states are doing in the area related to PBM regulation and outlining and defining general issues that states might want to consider if they are looking to regulate PBMs. He acknowledged that the white paper might not be perfect and probably will never be perfect, but it is a good resource for state insurance regulators to obtain information on issues related to PBM regulation and the role PBMs play in the prescription drug ecosystem. He said that for these reasons, Pennsylvania supports the PBM white paper's adoption. Director Lindley-Myers expressed support for Commissioner Humphreys' comments. Although Missouri is not a Task Force member, she urged the Task Force to adopt the PBM white paper as a resource for state insurance regulators to use if they like to help inform them on issues related to the PBM regulation and the role they play in the prescription drug ecosystem.

Chris Petersen (Arbor Strategies LLC), speaking on behalf of the PCMA, said the PCMA supports Connecticut's, Kansas', Nebraska's, and North Dakota's comments. He said that in reading the comments submitted to the Task Force, there is still significant concern with the PBM white paper. He said that typically before an NAIC product is considered for adoption, all the issues are worked out and there is consensus. He said the PCMA is afraid that in adopting the current version of the PBM white paper, stakeholders not involved in the drafting process will believe that it is a consensus document when there is still significant opposition to some of its provisions. Therefore, he said the PCMA urges the Task Force not to adopt it.

J.P. Wieske (Horizon Government Affairs—HGA) discussed the history related to the PBM white paper. He explained that when he chaired the Task Force on behalf of Wisconsin, in 2018, the Task Force established the Pharmacy Benefit Manager Regulatory Issues (B) Subgroup because of the discussion by the Executive (EX) Committee members and Plenary during the adoption of the revisions to the *Health Carrier Prescription Drug Benefit Management Model Act* (#22). He said concerns were raised that the revisions to Model #22 did not directly regulate the activities of PBMs in their role as managers of prescription drug benefits. He noted that after the proposed PBM model, which would have established a licensing or registration process for PBMs, failed to receive sufficient votes for adoption, the Subgroup turned to developing a white paper to educate state insurance regulators on PBM regulation and the role PBMs play in the prescription drug ecosystem because of this strong interest in learning more about these issues.

Commissioner Clark acknowledged the comments from Task Force members and interested parties. She said the white paper is not perfect given the myriad of different stakeholder perspectives and opinions. She said that despite this, she believes the PBM white paper is a good resource for state insurance regulators to learn more about the issues. She also noted the federal government's interest in these issues as well. She urged the Task Force members to adopt the white paper and forward it to the Health Insurance and Managed Care (B) Committee for its consideration and next steps.

Keen made a motion, seconded by Scott, to adopt the white paper, as revised, and include in an appendix the comments received by the Task Force on the July 27 version of the white paper (Attachment Two). The motion passed with: 1) the following Task Force members voting in favor of the motion: Alaska, Iowa, Maine, New Hampshire, Oklahoma, Oregon, Pennsylvania, Texas, Utah, Virginia, Washington, and Wisconsin; 2) the following Task Force members voting against the motion: Connecticut, Kansas, Nebraska, North Carolina, North Dakota, and South Dakota; and 3) the following Task force members abstaining: Idaho, Indiana, Massachusetts, and West Virginia.

Having no further business, the Regulatory Framework (B) Task Force adjourned.

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Draft Pending Adoption

Draft: 8/21/23

Regulatory Framework (B) Task Force
Seattle, Washington
August 13, 2023

The Regulatory Framework (B) Task Force met in Seattle, WA, Aug. 13, 2023. The following Task Force members participated: Sharon P. Clark, Chair (KY); Glen Mulready, Vice Chair, represented by Andy Schallhorn (OK); Michael Conway represented by Debra Judy and Jason Lapham (CO); Andrew N. Mais represented by Jared Kosky (CT); Karima M. Woods represented by Yohannes Negash (DC); Doug Ommen represented by Andria Seip (IA); Dean L. Cameron represented by Weston Trexler (ID); Amy L. Beard represented by Alex Peck (IN); Vicki Schmidt represented by Julie Holmes (KS); Gary D. Anderson represented by Kevin Beagan (MA); Timothy N. Schott represented by Marti Hooper and Robert Wake (ME); Grace Arnold represented by Peter Brickwedde (MN); Jon Godfread represented by Chrystal Bartuska (ND); Eric Dunning represented by Maggie Reinert, Michael Muldoon, and Margaret Garrison (NE); D.J. Bettencourt (NH); Justin Zimmerman (NJ); Judith L. French represented by Laura Miller (OH); Andrew R. Stolfi represented by TK Keen (OR); Michael Humphreys (PA); Larry D. Deiter represented by Jill Kruger (SD); Cassie Brown represented by Rachel Bowden (TX); Jon Pike represented by Tanji J. Northrup (UT); Scott A. White represented by Julie Blauvelt and Jackie Myers (VA); Mike Kreidler represented by Ned Gaines (WA); Nathan Houdek represented by Jennifer Stegall and Rebecca Rebholz (WI); and Allan L. McVey represented by Erin K. Hunter and Joylynn Fix (WV). Also participating were: Erica Weyhenmeyer (IL); and Jane Beyer (WA).

1. Adopted its Spring National Meeting Minutes

Keen made a motion, seconded by Seip, to adopt the Task Force's March 22 minutes (*see NAIC Proceedings – Spring 2023, Regulatory Framework (B) Task Force*). The motion passed unanimously.

2. Adopted its Subgroup and Working Group Reports

Before asking for a motion to adopt the Task Force's subgroup and working group reports, Commissioner Clark explained that in adopting the Pharmacy Benefit Manager Regulatory Issues (B) Subgroup's report and minutes, the Task Force is not adopting the pharmacy benefit manager (PBM) white paper, which the Subgroup adopted during its July 27 meeting. The Task Force plans to meet following the Summer National Meeting to discuss its next steps for the white paper.

Gaines made a motion, seconded by Seip, to adopt the following reports: 1) the Accident and Sickness Insurance Minimum Standards (B) Subgroup, including its Aug. 7 (Attachment One), July 24 (Attachment Two), July 10 (Attachment Three), June 29 (Attachment Four), May 15 (Attachment Five), April 24 (Attachment Six), April 17 (Attachment Seven), and March 27 (Attachment Eight) minutes; 2) the Employee Retirement Income Security Act (ERISA) (B) Working Group, including its Aug. 13 (Attachment Nine) minutes; 3) the Mental Health Parity and Addiction Equity Act (MHPAEA) (B) Working Group, including its March 23 (Attachment Ten) minutes; and 4) the Pharmacy Benefit Manager Regulatory Issues (B) Subgroup, including its July 27 (Attachment Eleven) minutes. The motion passed unanimously.

3. Heard a Panel Discussion on Prior Authorization

Lucy Culp (Leukemia & Lymphoma Society—LLS), Emily Carroll (American Medical Association—AMA) and Beyer discussed prior authorization. Culp discussed patient and consumer experiences with prior authorization and how the prior authorization process can create a barrier to care. She highlighted a 2023 Kaiser Family Foundation (KFF) survey of consumer experiences with health insurance, which showed that six in 10 insured adults reported problems with their health insurance in the past year. Culp also discussed the NAIC consumer representatives'

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work group on prior authorizations, appeals, and denials, including its areas of focus. She also identified opportunities and key policy reforms the states can take to address patient and consumer needs to: 1) improve access to evidence-based care; 2) ensure continuity of care; 3) promote transparency and fairness; 4) improve timely access to care; and 5) reduce administrative barriers.

Carroll discussed how prior authorization can harm patients, be burdensome to physician practices, and waste overall health care resources. She also discussed opportunities and solutions for state insurance regulators to reform the prior authorization process and provided examples of how certain states, including Washington, are acting on those solutions to reform the prior authorization process. Carroll also discussed federal actions complementing state actions to reform the prior authorization process.

Beyer discussed prior authorization in Washington, including the prior authorization rules adopted in 2017 and legislation enacted in 2023. She explained that Washington's prior authorization requirements apply to all health services, including prescription drugs. Washington requires carriers to use evidence-based clinical review criteria that are updated at least annually and can accommodate evidence regarding appropriate care for people of color and gender differences. Beyer said Washington's prior authorization requirements also include timeliness standards. She noted that Washington considers a prior authorization denial to be an adverse benefit determination that the health care provider or consumer can appeal.

Beyer discussed Washington's requirements for carriers to have a secure online process for a health care provider or facility to use to: 1) determine whether prior authorization is required; 2) find applicable clinical criteria and required documentation; and 3) submit prior authorization request with any needed documentation. She said that Washington has added new requirements for the online process to allow a health care provider or facility to submit and obtain a response to prior authorization requests using an application programming interface (API) beginning in 2025 for health care services (or 2026 if the federal interoperability proposed rule is not finalized by Sept. 13, 2023) and beginning in 2027 for prescription drugs.

Beyer discussed Washington's findings on how carriers use prior authorization based on the data it receives in accordance with its data reporting law, which was effective in 2020. She said that based on the data received, the services most frequently subject to prior authorization are: 1) physical therapy; 2) colonoscopy/endoscopy; 3) continuous positive airway pressure (CPAP) device; 4) imaging, including computed tomography (CT) and magnetic resonance imaging (MRI); and 5) room and board for both medical and behavioral health. She discussed the findings from a review of 2021 data for services with an approval rate of 98% or more and at least 50 requests processed. She highlighted the average standard response times for prior authorization requests from this review for current procedural terminology (CPT)/Healthcare Common Procedure Coding System (HCPCS) codes with the most prior authorization requests for medical-surgical versus mental health/substance use disorder (MH/SUD). She said the data showed that carriers generally take longer to approve or deny prior authorization requests for mental health/substance use disorder services than for medical-surgical services. She said the states can use this type of data as an indicator, operationally, of what more may be needed for comparability between the provision of MH/SUD services and medical-surgical services.

Having no further business, the Regulatory Framework (B) Task Force adjourned.

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Agenda Item #2

Consider Adoption of its Subgroup and Working Group Reports

—Commissioner Sharon P. Clark (KY)

- *Accident and Sickness Insurance Minimum Standards (B) Subgroup*
—Andy Schallhorn (OK) and Rachel Bowden (TX)
- *Employee Retirement Income Security Act (ERISA) (B) Working Group—Robert Wake (ME)*
- *Mental Health Parity and Addiction Equity Act (MHPAEA) (B) Working Group*
—Erica Weyhenmeyer (IL)
- *Pharmacy Benefit Manager Regulatory Issues (B) Subgroup—TK Keen (OR)*

Virtual Meetings

ACCIDENT AND SICKNESS INSURANCE MINIMUM STANDARDS (B) SUBGROUP

October 2, 2023 / September 18, 2023 / August 21, 2023

Summary Report

The Accident and Sickness Insurance Minimum Standards (B) Subgroup of the Regulatory Framework (B) Task Force met Oct. 2, Sept. 18, and Aug. 21, 2023. During these meetings, the Subgroup:

1. Completed its discussions of proposed revisions to the *Model Regulation to Implement the Accident and Sickness Insurance Minimum Standards Model Act (#171)* based on the comments received.
2. Exposed a revised draft of Model #171 for a public comment period ending Dec. 1.

Draft: 10/11/23

Accident and Sickness Insurance Minimum Standards (B) Subgroup
Virtual Meeting
October 2, 2023

The Accident and Sickness Insurance Minimum Standards (B) Subgroup of the Regulatory Framework (B) Task Force met Oct. 2, 2023. The following Subgroup members participated: Andy Schallhorn, Co-Chair (OK); Rachel Bowden, Co-Chair (TX); Chris Struk (FL); Frank Opelka (LA); Camille Anderson-Weddle (MO); Eric Dunning (NE); Shari Miles (SC); Tanji J. Northrup and Heidi Clausen (UT); Anna Van Fleet and Mary Block (VT); and Lichiou Lee (WA).

1. Continued Discussion of Section 9G of Model #171

The Subgroup continued its discussion of the proposed revisions to Section 9G—Limited Benefit Health Coverage (Outline of Coverage) of the *Model Regulation to Implement the Accident and Sickness Insurance Minimum Standards Model Act (#171)*. Jolie H. Matthews (NAIC) said that during its last meeting on Sept. 18, the Subgroup completed its review of Section 9G. She said that during its review, the Subgroup discussed what type of coverage would be considered limited benefit coverage under Model #171. However, the Subgroup did not reach any specific conclusion, but it agreed that this issue would need further discussion after the Subgroup completes its review of the comments received on Model #171. The Subgroup confirmed its decision.

2. Discussed Section 9H of Model #171

The Subgroup next discussed the NAIC consumer representatives' suggested language for the outline of coverage for short-term, limited-duration (STLD) health insurance coverage in Section 9H. Matthews reminded the Subgroup that for the consumer disclosure application language in Section 9A, the Subgroup agreed to use the consumer disclosure language in the federal proposed regulation for STLD plans, which is not reflected in the NAIC consumer representatives' suggested language. The Subgroup agreed to revise Section 9H(1) to reflect the Subgroup's previous discussion for the other outline of coverage provisions. In addition, the Subgroup asked NAIC staff to review and revise Section 9H(2) for consistency with the language in Section 9A for this product. In discussing Section 9H(3), the Subgroup agreed to not include the language "that would be covered by an Affordable Care Act qualified plan" because of the potential complexity for insurers to comply with this requirement due to the different and varied options for the type of benefits that can be included in STLD coverage in comparison to a federal Affordable Care Act (ACA) qualified plan. Consistent with its previous decisions, the Subgroup did not accept the NAIC consumer representatives' suggestion to add a provision requiring insurers to include a specific coverage example for an STLD health insurance coverage plan like those in the Summary of Benefits and Coverage.

3. Discussed Section 9I and J of Model #171

The Subgroup next discussed the NAIC consumer representatives' suggested language for the outline of coverage for limited-scope dental coverage in Section 9I and limited-scope vision in Section 9J. The Subgroup accepted the NAIC consumer representatives' suggested revisions for these provisions.

4. Discussed Section 10 of Model #171

The Subgroup next discussed the comments received on Section 10—Requirements for Replacement of Individual Supplementary and Short-Term Health Insurance Coverage. No comments were received on Section 10A.

The Subgroup discussed the NAIC consumer representatives' suggested revision for Section 10B to delete the provision excluding direct response insurers from the provision's requirements. The Subgroup discussed the implications of deleting this language and why the exclusion exists. After discussion, the Subgroup decided not to accept the NAIC consumer representatives' suggested revision because the Subgroup wants to retain the current framework of having two replacement notices—one for insurers other than direct response insurers under Section 10C and one for direct response insurers under Section 10D. The Subgroup reached this decision because of the slightly different language in the notices reflecting the fact that for direct response insurers, no insurance agent or company representative is involved in the initial transaction related to the policy being replaced.

The Subgroup discussed the NAIC consumer representatives' suggested revisions to Section 10C. The Subgroup agreed to accept the suggested revisions with a few stylistic changes, such as changing "may" to "might." The Subgroup also discussed the NAIC consumer representatives' suggested revisions to Section 10D, which are the same as those suggested for Section 10C. The Subgroup accepted the suggested revisions with the same stylistic changes as those agreed on for Section 10C.

Matthews said Section 10 is the last section for which the Subgroup requested comments from interested parties.

Jackson Williams (Dialysis Patient Citizens—DPC) reminded the Subgroup that he had submitted an article titled "Addressing Low-Value Insurance Products with Improved Consumer Information: The Case of Ancillary Health Products" during the Subgroup's public comment period for Sections 9 and 10. He said the information included in his article should be considered. The Subgroup discussed his request. After discussion, the Subgroup co-chairs said they would work with NAIC staff to determine the Subgroup's next steps regarding its work to revise Model #171.

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

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Draft: 10/5/23

Accident and Sickness Insurance Minimum Standards (B) Subgroup
Virtual Meeting
September 18, 2023

The Accident and Sickness Insurance Minimum Standards (B) Subgroup of the Regulatory Framework (B) Task Force met Sept. 18, 2023. The following Subgroup members participated: Andy Schallhorn, Co-Chair (OK); Rachel Bowden, Co-Chair (TX); Stephen F. Flick (DC); Chris Struk (FL); Camille Anderson-Weddle (MO); Maggie Reinert (NE); Shari Miles (SC); Shelley Wiseman and Heidi Clausen (UT); Anna Van Fleet, Mary Block, and Jamie Gile (VT); and Ned Gaines (WA).

1. Continued Discussion of Section 9E of Model #171

Before continuing its discussion of the comments received on Section 9E—Accident-Only Coverage (Outline of Coverage) of the *Model Regulation to Implement the Accident and Sickness Insurance Minimum Standards Model Act (#171)*, Jolie H. Matthews (NAIC) walked through a revised staff draft of proposed revisions to Section 9A—General Rules of Model #171 reflecting the Subgroup’s discussions up to its last meeting on Aug. 21. She explained that based on the Subgroup’s discussion during its Aug. 21 meeting, it seemed that in discussing the revisions to outline of coverage provisions in Section 9, the Subgroup is relying on revisions it has preliminarily approved for the consumer product statements in Section 9A. As such, she said she wants to walk through the Section 9A proposed revisions.

After completion of the review of the Section 9A proposed revisions, the Subgroup returned to its discussion of the NAIC consumer representatives’ suggested revisions to Section 9E. After discussion, the Subgroup confirmed its decision to revise the language in Section 9E(2) for consistency with the language in Section 9A for this type of coverage.

2. Discussed Section 9F of Model #171

The Subgroup next discussed the NAIC consumer representatives’ suggested revisions to Section 9F—Specified Disease or Specified Accident Coverage (Outline of Coverage) of Model #171. After discussion, the Subgroup decided to delete Section 9F(1). The Subgroup agreed to accept the suggested revisions to Section 9F(2). The Subgroup also agreed to revise Section 9F(3) for consistency with the language in Section 9A for this type of coverage and include the reference to the *Buyer’s Guide to Specified Disease Insurance* from Section 9F(1). Consistent with its previous discussions, the Subgroup did not accept the NAIC consumer representatives’ suggestion to add a provision requiring insurers to include a specific coverage example like those in the Summary of Benefits and Coverage for a specified disease or specified accident coverage.

3. Discussed Section 9G of Model #171

The Subgroup next discussed the NAIC consumer representatives’ suggested revisions to Section 9G—Limited Benefit Health Coverage (Outline of Coverage) of Model #171. The Subgroup agreed to accept the suggested revisions for Section 9G(1). Consistent with its previous discussions, the Subgroup agreed to revise Section 9G(2) for consistency with the language in Section 9A for this type of coverage. Also, consistent with its previous discussions, the Subgroup did not accept the NAIC consumer representatives’ suggestion to add a provision requiring insurers to include a specific coverage example like those in the Summary of Benefits and Coverage for limited benefit health coverage. The Subgroup also discussed what type of coverage would be considered limited benefit coverage under Model #171. The Subgroup did not reach any specific conclusion, but it agreed that this

issue would need further discussion after the Subgroup completes its review of the comments received on Model #171.

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

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Draft: 9/7/23

Accident and Sickness Insurance Minimum Standards (B) Subgroup
Virtual Meeting
August 21, 2023

The Accident and Sickness Insurance Minimum Standards (B) Subgroup of the Regulatory Framework (B) Task Force met Aug. 21, 2023. The following Subgroup members participated: Andy Schallhorn, Co-Chair (OK); Rachel Bowden, Co-Chair (TX); Debra Judy (CO); Stephen F. Flick (DC); Chris Struk (FL); Robert Wake (ME); Camille Anderson-Weddle (MO); Martin Swanson and Maggie Reinert (NE); Shari Miles (SC); Shelley Wiseman and Heidi Clausen (UT); Anna Van Fleet, Mary Block, and Jamie Gile (VT); and Lichiou Lee (WA).

1. Continued Discussion of Section 9B of Model #171

The Subgroup continued its discussion of the suggested revisions to the product statements in Section 9B—Outline of Coverage Requirements of the *Model Regulation to Implement the Accident and Sickness Insurance Minimum Standards Model Act* (#171). The Subgroup returned to its discussion of the NAIC consumer representatives' suggested revisions to Section 9B(2). The Subgroup specifically revisited the suggested revisions to the consumer notice language. After discussion, the Subgroup confirmed its decision to accept the suggested revisions.

2. Discussed Section 9C of Model #171

The Subgroup next discussed the NAIC consumer representatives' suggested revisions to Section 9C—Hospital Indemnity or Other Fixed Indemnity Coverage (Outline of Coverage) of Model #171. After discussion, the Subgroup agreed to accept the suggested revisions with some changes. The Subgroup decided to delete the sentence in Section 9C(1): "Only the actual [policy] [certificate] provisions control." The Subgroup decided that the sentence is unnecessary and could be confusing to consumers.

The Subgroup next discussed Section 9C(2). The Subgroup discussed whether the language in the last sentence explaining potential policy benefit limitations for this type of coverage is confusing. After discussion, the Subgroup decided to revise the sentence to: "The fixed amount state in your [policy] [certificate] may be less than what you are charged." The Subgroup also requested that NAIC staff review the language the Subgroup agreed to include in the application section for consistency.

The Subgroup next discussed Section 9C(3). No comments were received on this provision, but the Subgroup discussed whether the language should be revised for clarity to ensure that insurers understand what this provision requires. After discussion, the Subgroup decided to revise Section 9C(3) to state when benefits are payable/triggered, how long the benefits will be paid (duration), and the dollar amount of the benefits. The Subgroup also discussed whether the word "daily" should be deleted because the use of this word could be misleading and inaccurate for this type of coverage. The Subgroup decided to delete "daily." The Subgroup also requested that NAIC staff search the document to determine whether "daily" is used in other provisions of Model #171.

The Subgroup discussed and agreed not to accept the NAIC consumer representatives' suggestion to add a sentence to Section 9C requiring insurers to include a specific coverage example like those in the Summary of Benefits and Coverage because of the complexity of creating such a specific coverage example, given the nature of the product and the possibility that the coverage example could be misleading to consumers.

3. Discussed Section 9D of Model #171

Next, the Subgroup discussed the NAIC consumer representatives' suggested revisions to Section 9D—Disability Income Protection Coverage (Outline of Coverage) of Model #171. As discussed and decided for Section 9C(1), the Subgroup agreed to delete the sentence in Section 9D(1): "Only the actual [policy] [certificate] provisions control." The Subgroup next discussed the suggested revisions for Section 9D(2). Like its discussion for Section 9C(2), the Subgroup asked NAIC staff to align the language in this provision with the language in the application provisions. The Subgroup also asked NAIC staff to remove the references to "basic hospital, basic medical-surgical, or major medical expenses." After discussion of the last sentence in Section 9D(2), the Subgroup agreed to delete the word "may" and replace it with "might."

Like its decision for Section 9C, the Subgroup did not accept the NAIC consumer representatives' suggestion to add a provision requiring insurers to include a specific coverage example like those in the Summary of Benefits and Coverage for disability income protection coverage.

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

SharePoint/NAIC Support Staff Hub/Member Meetings/B CMTE/RFTF/Accident and Sickness Subgrp/Accident and Sickness Ins Min Stds Subgrp 8-21-23MtgMin.docx

EMPLOYEE RETIREMENT INCOME SECURITY ACT (ERISA) (B) WORKING GROUP

Summary Report

The Employee Retirement Income Security Act (ERISA) (B) Working Group last met Aug. 13, 2023. During that meeting, the Working Group:

1. Heard an update from the U.S. Department of Labor (DOL).
2. Discussed level funded plans.
3. Received an update on revisions the NAIC MEWA/Multiple Employer Trust (MET) chart.
4. Adjourned into regulator-to-regulator session, pursuant to paragraph 2 (pending investigations), paragraph 3 (specific companies, entities or individuals), and paragraph 8 (consideration of strategic planning issues relating to federal legislative and regulatory matters) of the NAIC Policy Statement on Open Meetings.

2023 Fall National Meeting

Orlando, Florida

MENTAL HEALTH PARITY AND ADDICTION EQUITY ACT (B) WORKING GROUP

Saturday, December 2, 2023

11:30 a.m. – 12:15 p.m.

Meeting Summary Report

The Mental Health Parity and Addiction Equity Act (B) Working Group met Dec. 2, 2023. During this meeting, the Working Group:

1. Heard a panel discussion with participation from AHIP, the American Psychiatric Association (APA), and The Kennedy Forum. Panelists described their organizations' views of the mental health parity regulations recently proposed by the U.S. Department of Labor (DOL), the U.S. Department of Health and Human Services (HHS), and the U.S. Department of the Treasury (Treasury Department).

Draft: 8/24/23

Mental Health Parity and Addiction Equity Act (MHPAEA) (B) Working Group
Seattle, Washington
August 14, 2023

The MHPAEA (B) Working Group of the Regulatory Framework (B) Task Force met in Seattle, WA, August 14, 2023. The following Working Group members participated: Erica Weyhenmeyer, Chair (IL); Jane Beyer, Vice Chair (WA); Jimmy Harris (AR); Erin Klug (AZ); Kate Harris (CO); Kurt Swan (CT); Howard Liebers (DC); Andria Seip (IA); Julie Holmes (KS); Mary Kwei (MD); Paul Hanson (MN); Carrie Couch (MO); Ted Hamby (NC); Chrystal Bartuska (ND); DJ Bettencourt (NH); Ralph Boeckman (NJ); Paige Duhamel (NM); Laura Miller (OH); Ashley Scott (OK); Lindsy Swartz (PA); Glynda Daniels (SC); Jill Kruger (SD); Rachel Bowden and Matthew Tarpley (TX); Tanji J. Northrup (UT); Julie Blauvelt and Julie Fairbanks (VA); Barbara Belling (WI); Erin K. Hunter (WV), and Tana Howard (WY). Also participating was Kevin Beagan (MA).

1. Heard Presentations on Autism Treatment Standards

Lorrie Unumb (Council of Autism Service Providers) said more than 330 service providers are members of CASP, whose mission is to advocate for best practices in autism services. She highlighted a resource from CASP, *Applied Behavior Analysis: Treatment of Autism Spectrum Disorder*. She said every practitioner who utilizes applied behavior analysis should abide by the standards outlined in document and payers should incorporate it into their medical necessity standards. She said CASP offers training on the guidelines to payers and others.

Daniel Unumb (Autism Legal Resource Center) said ABA is the most proven and effective evidence-based treatment for conditions related to autism. He said ABA is not a typical treatment regime because of its tiered service delivery model, with a certified or licensed behavior analyst supervising behavior technicians, sometimes with a middle tier of assist behavior analysts.

Daniel Unumb said exclusions for ABA are not as common for fully-insured plans as for self-insured plans. For individual market plans, he said cover is often mandated by a state's essential health benefits. But where that is not the case, there is case law stating that ABA exclusions violate MHPAEA. He cited *Doe v. United Behavioral Health*.

Daniel Unumb said quantitative treatment limitations are rare for fully-insured plans. He said self-insured plans may include limits because a state mandate includes limiting language. They may no longer be applied, but could have a chilling effect on providers. He said some insurers impose caps on certain assessment codes, but this is not consistent with generally accepted professional standards and often violates the "substantially all" test under MHPAEA. He said one insurer's medical necessity criteria includes a cap on hours, which is inconsistent with the CASP guidelines. He said caps on speech, occupational, or physical therapy may also violate MHPAEA even if a similar cap is applied for medical conditions because of the substantially all test.

Daniel Unumb described several nonquantitative limits (NQTLs) of concern. He said some plans limit who may diagnose autism or what assessment tools may be used. He said prior authorization or the need for a treatment plan may be applied more stringently than they are for medical conditions. He said requirements for progress and the need for each treatment step to have a clear evidence base are not generally present for medical conditions. He said a need for parent participation is often inappropriate and is not applied on the medical side. He said some plans require that a certain percentage of treatment goals be met, which is not something applied to medical conditions.

Daniel Unumb said CASP and the Autism Legal Resource Center host an Autism Law Summit that brings together payers, providers, families, regulators, and other stakeholders for informal, educational discussions.

Seip asked about Doe v. UBH. Daniel Unumb said the case concluded that an exclusion of ABA violated two prongs of MHPAEA, that the exclusion was applied only to mental health and eliminated the core treatment for autism.

Beyer asked about state legislation to require medical necessity standards to recognize generally accepted standards of care and whether states with these laws have better coverage of ABA. She also said some carriers limit ABA only to autism spectrum disorders and not allow it for other intellectual developmental disorders (IDDs). Lorrie Unumb said California in particular has legislation on medical necessity and regulations in that state specifically cite CASP guidelines. She said the state is seeing progress. Daniel Unumb said limits on ABA for IDDs other than autism would violate anti-discrimination law in Section 1557 if it is a disabling condition and could violate MHPAEA if the condition is a mental health condition.

Couch asked about denials of services during transition to adulthood. Daniel Unumb said that is an area of discrimination even though many studies show ABA is effective for adults.

Duhamel said age limits may be discriminatory under essential health benefits requirements and Section 1557. She said New Mexico's law requires insurers to cover ABA regardless of whether they are ordered or provided in school. Daniel Unumb said California law also requires coverage regardless of whether other entities have coverage obligations.

Having no further business, the MHPAEA (B) Working Group adjourned into regulator-to-regulator session, pursuant to paragraph 8 (consideration of strategic planning issues) of the NAIC Policy Statement on Open Meetings, to continue work on its goals.

SharePoint/NAIC Support Staff Hub/Member Meetings/B CMTE/RFTF/MHPAEAWG Min 8.14.docx

PHARMACY BENEFIT MANAGER REGULATORY ISSUES (B) SUBGROUP

Summary Report

The Pharmacy Benefit Manager Regulatory Issues (B) Subgroup last met July 27, 2023. During that meeting, the Subgroup:

1. Adopted its April 17 and Spring National Meeting minutes. During its April 17 meeting, the Subgroup exposed the pharmacy benefit manager (PBM) white paper for a 45-day public comment period ending June 1.
2. Adopted the PBM white paper and forwarded it to the Regulatory Framework (B) Task Force for its consideration.

Agenda Item #3

Hear a Presentation on the Results and Impact of the Copay Accumulator Adjustment Programs Lawsuit—*Carl Schmid (HIV + Hepatitis Policy Institute)*

Legal Update: Results and Impact of the Copay Accumulator Adjustment Lawsuit

Carl Schmid
Executive Director
HIV+Hepatitis Policy Institute

NAIC Regulatory Framework (B) Task Force
December 1, 2023





Patient Groups File Suit to End Policy That Prohibits Copay Assistance from Counting Toward Patients' Out-of-Pocket Spending

Harmful Insurer & PBM Policy Increases Prescription Drug Costs for Patients

WASHINGTON (August 30, 2022) – Today, the [HIV+Hepatitis Policy Institute](#), the [Diabetes Leadership Council](#) (DLC), and the [Diabetes Patient Advocacy Coalition](#) (DPAC), representing 42 million people, [filed suit](#) in the U.S. District Court for the District of Columbia challenging a federal rule that allows health insurers to avoid counting the value of drug manufacturer copay assistance toward patients' out-of-pocket cost obligations.

ACA Violations

- ▶ **Insurers collect more than cost-sharing caps**
- ▶ **ACA Definition of cost-sharing:**
 - “deductibles, coinsurance, copayments, or similar charges; *and any other expenditure required of an insured individual* which is a qualified medical expense.”
 - Does not indicate where money comes from
- ▶ **ACA regulations for cost-sharing**
 - “any expenditure required by *or on behalf of an enrollee* with respect to essential health benefits,” including deductibles, coinsurance, copayments, or similar charges”

Arbitrary & Capricious

- ▶ **Allows insurers to decide if copay assistance can count or not**
 - They decide what constitutes cost-sharing
- ▶ **2020 Rule Abandoned w/o explanation**
 - Failed to present options
 - IRS Guidance on Discount Cards can't trump law
 - Further, not related to copay assistance
- ▶ **2021 Rule**
 - Assumed that use of copay accumulators would not increase

Administrative Procedures Act Complaint

▶ Requested Relief

- Set aside provision in 2021 NBPP rule allowing copay accumulators
- Declare that copay accumulators are illegal

Timeline of Key Events

- ▶ **Government Moves to Dismiss (Oct. 2022)**
- ▶ **Plaintiffs add 3 patients impacted by accumulators (Nov. 2022)**
- ▶ **Briefing Schedule Agreed to by all Parties) (Dec. 2023)**
 - Last brief due April 2023
- ▶ **Plaintiffs File Motion for Summary Judgment (Feb. 2023)**

Amicus Brief – Patient Community

- ▶ **Aimed Alliance**
- ▶ ADAP Advocacy Association
- ▶ Advocacy & Awareness for Immune Disorders Association
- ▶ Any Positive Chance
- ▶ The Association of Community Cancer Centers (ACCC)
- ▶ Autoimmune Association
- ▶ Chronic Care Policy Alliance (CCPA)
- ▶ Coalition of State Rheumatology Organizations
- ▶ Community Access National Network (CANN)
- ▶ Connecticut Oncology Association
- ▶ Community Oncology Alliance
- ▶ Equitas Health
- ▶ EveryLife Foundation for Rare Diseases
- ▶ Fabry Support & Information Group
- ▶ Gaucher Community Alliance

Amicus Brief – Patient Community

- ▶ Georgia AIDS Coalition
- ▶ Global Liver Institute
- ▶ Global Healthy Living Foundation
- ▶ Healthy Men Inc.
- ▶ Hemophilia Federation of America (HFA)
- ▶ International Cancer Advocacy Network (ICAN)
- ▶ Infusion Access Foundation
- ▶ International Foundation for Autoimmune & Autoinflammatory Arthritis
- ▶ National Health Law Program (NHeLP)
- ▶ National Infusion Center Association (NICA)
- ▶ National Consumers League (NCL)
- ▶ National Oncology State Network
- ▶ Rheumatology Nurses Society
- ▶ Triage Cancer

Amicus Brief - TrialCard

“the insurer pockets the full out-of-pocket maximum **plus** the amounts received through manufacturer assistance, resulting in a substantial windfall for the insurers while harming patients for whose benefit the assistance was intended.”

“TrialCard’s own internal data bear out these concerns. The data indicate that patients cease using drugs when accumulator programs are in effect.”

Amicus Brief - PhRMA

“This allows for the collection of the manufacturer’s cost-sharing assistance, *as well as* the full amount of the patient’s deductible or out-of-pocket maximum”

“The agencies appeared to misunderstand this basic feature of manufacturer cost-sharing assistance. According to HHS, this assistance might be viewed as “reducing the costs incurred by an enrollee under the health plan” because the assistance would “reduce the amount that the enrollee is required to pay in order to obtain coverage for the drug.”

...But these ...**programs do not reduce the total amount the patient owes to the pharmacy; they operate as an additional funding source to pay for a patient’s medication.**”

Government Brief

- ▶ Submitted after a 2-week extension (March 2023)
- ▶ No longer seeking dismissal of case

“it is **not accurate to say**, as Plaintiffs do throughout their brief, that **insurance companies “collect” the value of manufacturer coupons** through their accumulator adjustment programs...Rather, accumulator adjustment programs allow issuers and plans to **delay incurring coverage liability** until after the enrollee has satisfied the amount of the required cost sharing without including the amount of the manufacturer assistance”

Government Brief

- ▶ Plaintiffs' claims are **nonjusticiable** because the rule is not final agency action...the rule declines to set definite requirements in this area and provides complete flexibility to states
- ▶ HHS properly concluded that the relevant statute is ambiguous as to whether the value of manufacturer financial assistance counts as cost sharing, and **HHS's decision to permit flexibility in this area is not arbitrary or capricious.**
- ▶ If court rules HHS acted in an arbitrary and capricious manner, **should remand case back for further rulemaking**, and not make decision on definition of cost-sharing

Amicus Brief - AHIP

“Co-pay accumulator programs have been developed **to mitigate the market distortion that coupons cause**. Accumulators operate on a simple premise: when a manufacturer discounts its price through a co-pay coupon, the discount does not require the patient to incur any cost, so it does not count toward a patient’s cost-sharing. This preserves important cost-sharing incentives that help nudge patients toward lower cost, higher value choices.”

“**Accumulators thus let patients benefit from the coupon discount**—the patient’s out-of-pocket spending is still reduced or eliminated whenever a coupon is available, and the accumulator does not change that. **Nor does the accumulator provide a windfall to health insurance providers, because the manufacturer pays the value of the co-pay coupon to the pharmacy (not the health insurance provider).**”

Amicus Brief - AHIP

“Co-pay coupons are discounts. Copay accumulator programs do not stop patients from accessing those discounts, but simply ensure that such discounts actually reduce the total amount spent overall by the patient and health plan (and thus all consumers) on prescription drugs, rather than being used to inflate drug prices and drug spending. This is not a ‘windfall’ to health insurance providers. Instead, it lowers the cost of health care for everyone.”

Plaintiffs Response Brief

- ▶ **Filed after an 18-day extension (May 2023)**
- ▶ Ok, insurers may not technically collect the coupons but “government acknowledges that such programs seek to shift drug costs from insurers to patients and manufacturers” & “the net economic result is precisely the same”
- ▶ No merit in argument that despite copay rule “the agencies’ action is *actually* a “decision *not* to set definitive standards in this area.”

Government's Response Brief

- ▶ **Filed July 14th after 3 extensions, 53 days late**
- ▶ Rule issued because confusion with IRS guidelines
- ▶ Barring copay accumulators will lead to higher drug prices
- ▶ Copay assistance provides patients with a reduction in their costs offered by the drug manufacturers and therefore patient not responsible for it and it is not “cost-sharing”
- ▶ Government did not issue any legal requirements but let states decide



Court Strikes Down HHS Rule that Allowed Insurers to Not Count Copay Assistance

Copay Assistance for Drugs Must Now Count in Most Instances

WASHINGTON (October 2, 2023) – In a major victory for patients who depend on prescription drugs, Judge John D. Bates of the U.S. District Court for the District of Columbia [struck down](#) a Trump administration federal rule that allowed health insurers to not count drug manufacturer copay assistance towards a beneficiary’s out-of-pocket costs.

The [case](#) was brought against the U.S. Department of Health and Human Services by the [HIV+Hepatitis Policy Institute](#), [Diabetes Leadership Council](#), [Diabetes Patient Advocacy Coalition](#), and three patients who depend on copay assistance and whose insurers implemented “copay accumulator” policies.

Court Decision

- ▶ **VICTORY! Vacated 2021 Notice of Benefit and Payment Parameters Rule that allows copay accumulators**

“the Court will set aside the 2021 NBPP based on both its contradictory reading of the same statutory and regulatory language and the fact that the agencies have yet to offer a definitive interpretation of this language that would support their authorization of copay accumulators.”

- ▶ Agencies can't allow for the same meaning of a law and regulation to be chosen at the discretion of regulated parties. It is arbitrary and capricious.

Not a Complete Victory

- ▶ **ACA law** is not clear as to if manufacture assistance must count as cost-sharing
 - Therefore, vacate the rule & remand to permit the agencies to interpret the statutory definition
- ▶ **ACA regulation** that cost sharing is “any expenditure required by or on behalf of an enrollee” seems to conflict with 2021 NBPP.
 - Agrees, based on arguments presented by plaintiffs
 - While rejecting government’s arguments
 - But there could be another meaning: “required by” could mean the enrollee is requiring it & finds that odd
 - So asks agencies to grapple with this

Judge's Opinion

- ▶ **Fully understood and stated how copay assistance & accumulators work:**
 - Increase patient's costs
 - Increase manufacturer costs
 - Increase payments to insurers
 - Is not a discount from the cost of the drug
- ▶ **Didn't accept government argument that case was unjustifiable**
 - Rule was part of US Federal Code & had legal consequences

Judge's Opinion

- ▶ **Did not address that insurers collecting more money than permitted under ACA cost-sharing limits & double billing**
- ▶ **Did not address the IRS guidance issue with High Deductible HSA's**
- ▶ **Did not address other claims on why rule was arbitrary & capricious**
- ▶ **Did not declare copay accumulators illegal & didn't address copay maximizers**
 - Although it should ban maximizers for EHB drugs

Next Steps

- ▶ **2020 NBPP now in effect**

- Regulation: Accumulators may be allowed for brand name drugs w/ generic alternative, if permitted by state law

- Preamble: Copay assistance must count for brands w/o generic

- ▶ **Judge did not stay the decision so impact immediate**

- ▶ **Federal Government Filed Motion to Clarify Ruling**

- Will issue rule on definition of cost-sharing

- In meantime, will not enforce court decision

- ▶ **Federal Government Appealed Decision**

- ▶ **Plaintiffs will oppose/fight both**

- ▶ **Federal & State Enforcement Needed**

- ▶ **Congressional & State legislation**

2020 Notice of Benefits & Payment Parameters Rule

“Notwithstanding any other provision of this section, and to the extent consistent with state law, **amounts paid toward cost sharing using any form of direct support offered by drug manufacturers** to enrollees to reduce or eliminate immediate out-of-pocket costs for specific prescription brand drugs that **have an available and medically appropriate generic equivalent are not required to be counted toward the annual limitation on cost sharing** (as defined in paragraph (a) of this section).

Thank you!

<https://hivhep.org/copay-accumulator-litigation/>

Carl Schmid

cschmid@hivhep.org

Follow: @HIVHep

HIV + HEP

POLICY INSTITUTE

Agenda Item #4

Hear a Presentation on “Cost: The Greatest Barrier to Access”

—*Jessica Brooks-Woods (National Association of Benefits and Insurance Professionals (NABIP))*



Jessica Brooks-Woods, CEO NABIP

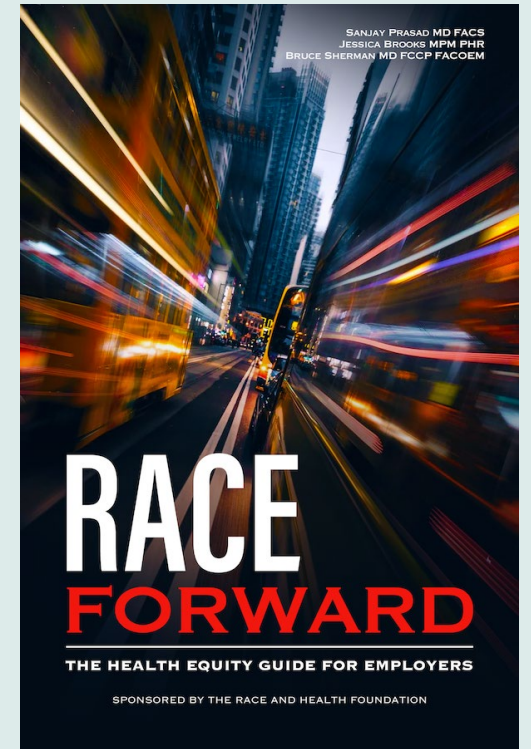
Cost: The Greatest Barrier to Access

**HAVE
YOU HEARD**

NAHU is now

NABIP

Shaping the *future* of healthcare

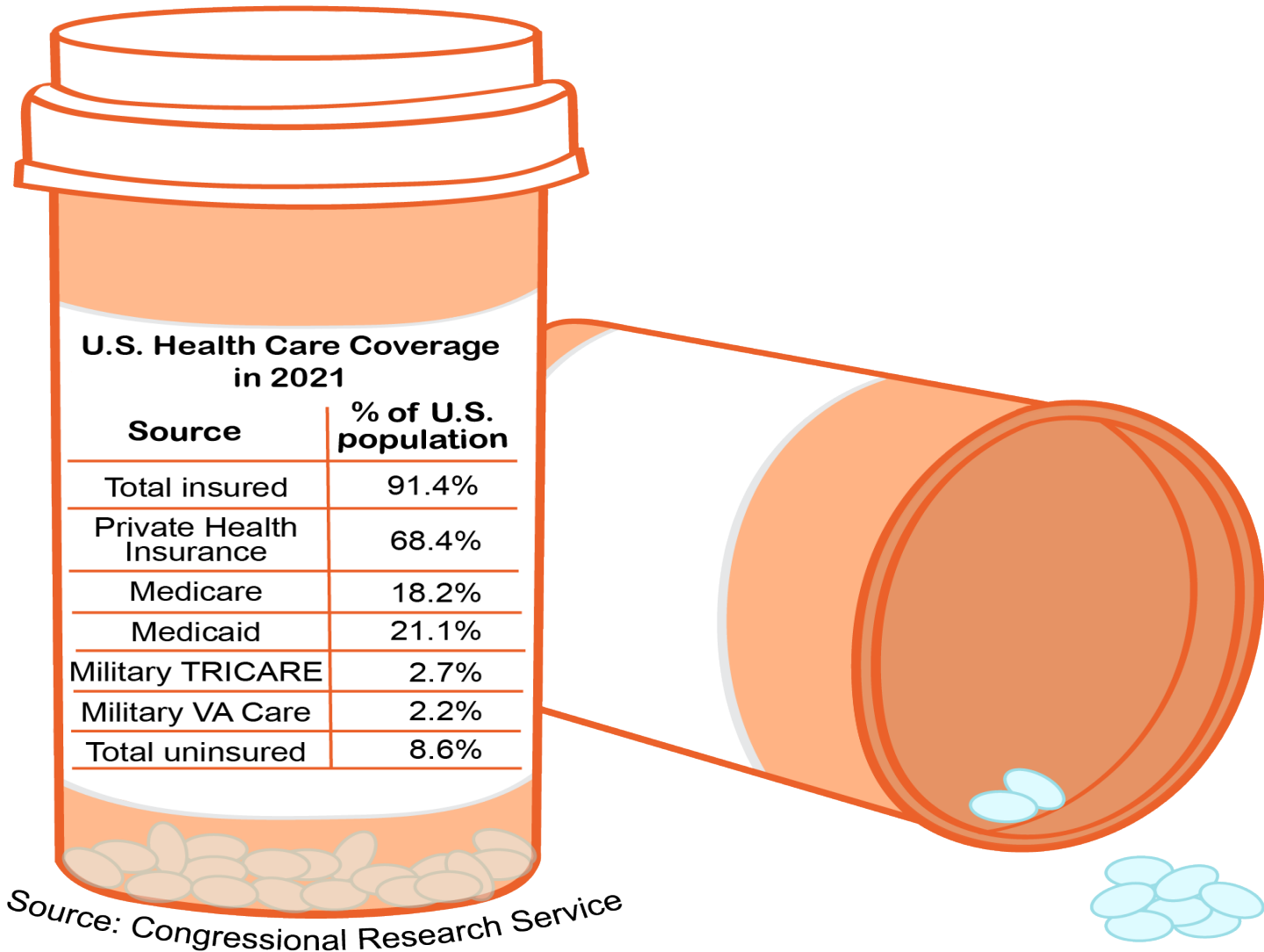


What is
keeping health
insurance
brokers up at
night?

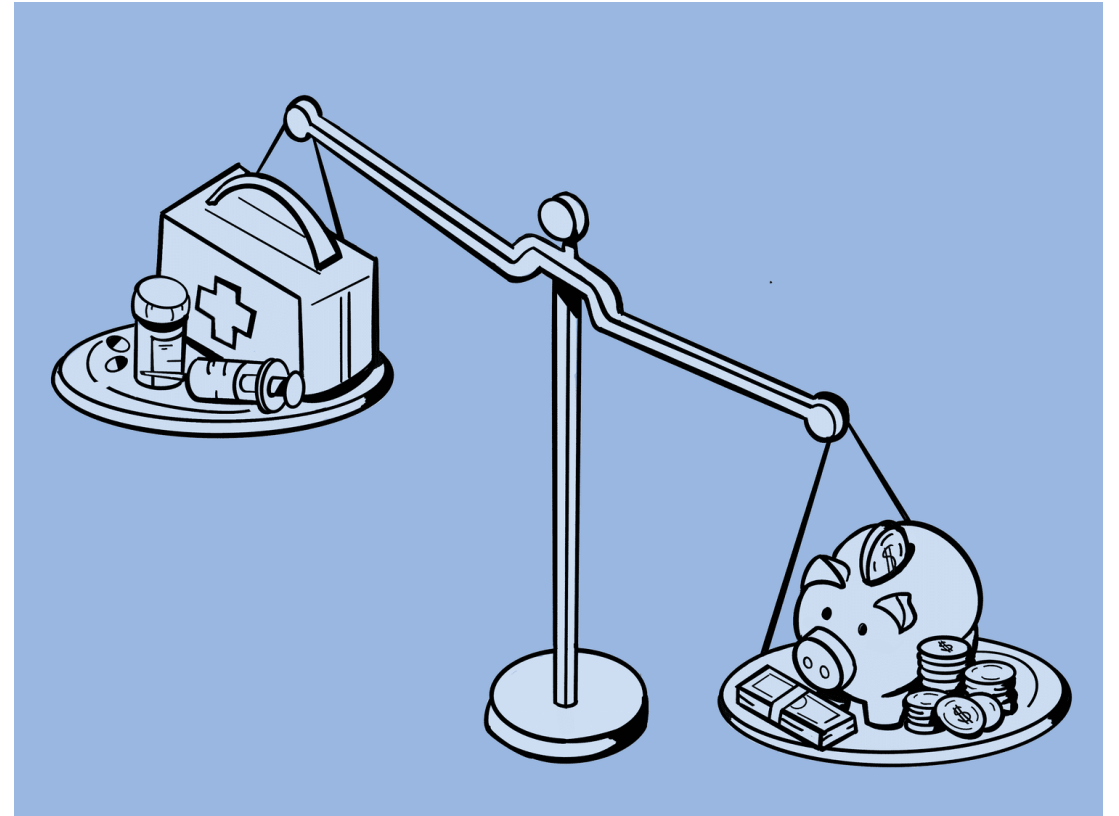




So, where
are we
today?

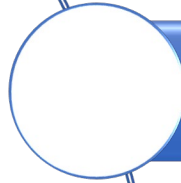


Health-care utilization is determined by the need for care, by whether people know that they need care, by whether they want to obtain care, and ***by whether care can be accessed.***

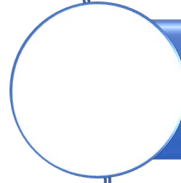




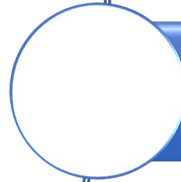
About half of U.S. adults say they have difficulty affording health care costs.



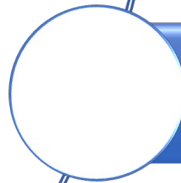
Substantial shares of adults 65 or older report difficulty paying for various aspects of health care



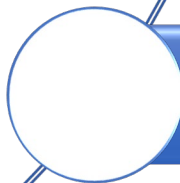
The cost of health care often prevents people from getting needed care or filling prescriptions.



High health care costs disproportionately affect uninsured adults, Black and Hispanic adults, and those with lower incomes



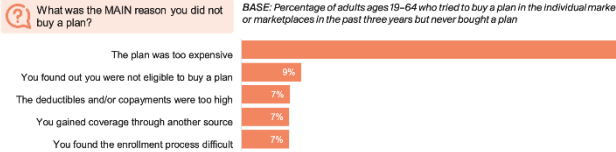
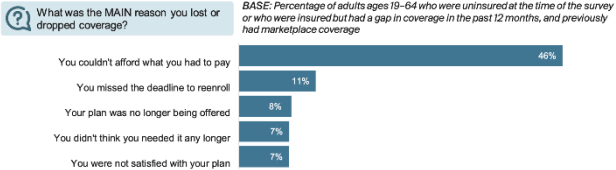
Those who are covered by health insurance are not immune to the burden of health care costs.



Health care debt is a burden for a large share of Americans

With cost trends like these, it's no wonder we have an access issue!

Premium costs are the main reason people give for not buying marketplace or individual market coverage or for dropping their coverage.

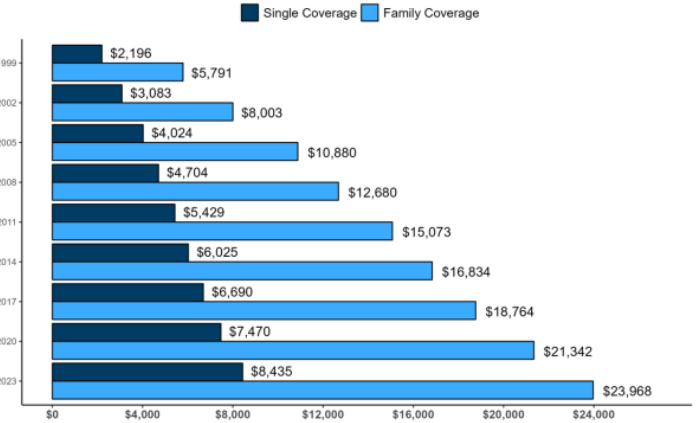


Data: Commonwealth Fund Biennial Health Insurance Survey (2022).

Source: Sara R. Collins, Lauren A. Haynes, and Relebohile Mashele, *The State of U.S. Health Insurance in 2022: Findings from the Commonwealth Fund Biennial Health Insurance Survey* (Commonwealth Fund, Sept. 2022) <https://doi.org/10.26099/73g-3432>



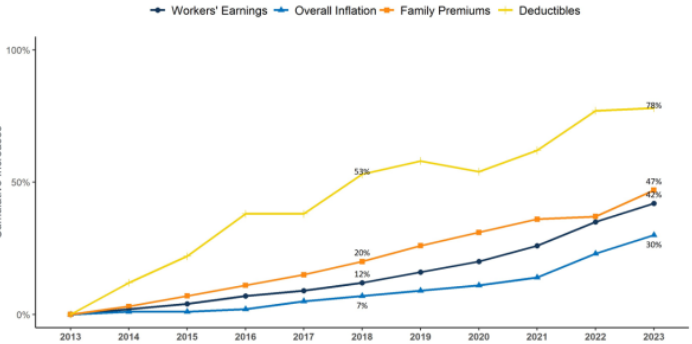
Figure 1
Average Annual Premiums for Single and Family Coverage, 1999-2023



SOURCE: KFF Employer Health Benefits Survey, 2018-2023; KaiserHRET Survey of Employer-Sponsored Health Benefits, 1999-2017



Figure 6
Cumulative Increases in Family Coverage Premiums, General Annual Deductibles, Inflation, and Workers' Earnings, 2013-2023



NOTE: Average general annual deductibles are for single coverage and are among all covered workers. Workers in plans without a general annual deductible for in-network services are assigned a value of zero.
SOURCE: KFF Employer Health Benefits Survey, 2018-2023; KaiserHRET Survey of Employer-Sponsored Health Benefits, 2013-2017; Bureau of Labor Statistics, Consumer Price Index, U.S. City Average of Annual Inflation, 2013-2023; Bureau of Labor Statistics, Seasonally Adjusted Data from the Current Employment Statistics Survey, 2013-2023.

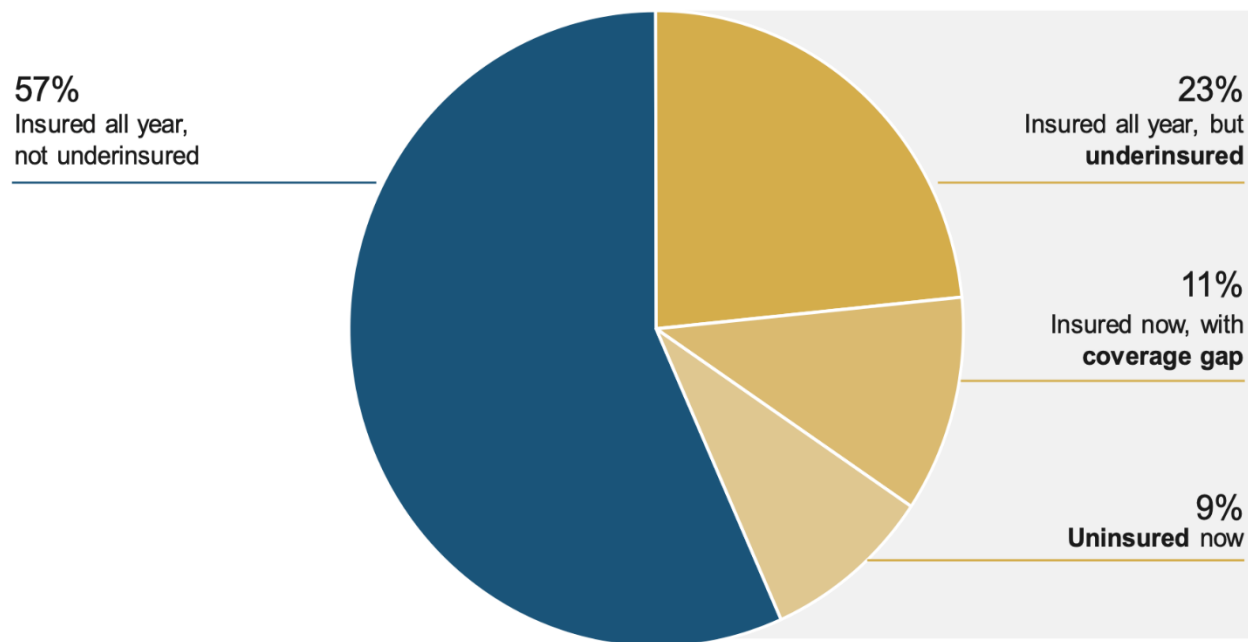


The problem extends to those with insurance coverage...

“Twenty-nine percent of people with employer coverage and 44 percent of those with coverage purchased through the individual market and marketplaces were underinsured.”

Finding from the 2022 Commonwealth Fund Biennial Health Insurance Survey

Percentage of adults ages 19–64, by insurance coverage status within the past 12 months



Notes: “Insured all year, but underinsured” refers to adults who were insured all year but experienced one of the following: out-of-pocket costs, excluding premiums, equaled 10% or more of household income; out-of-pocket costs, excluding premiums, equaled 5% or more of household income if low-income (<200% of poverty); or deductibles equaled 5% or more of household income. “Insured now, with coverage gap” refers to adults who were insured at the time of the survey but were uninsured at any point in the 12 months prior to the survey field date. “Uninsured now” refers to adults who reported being uninsured at the time of the survey.

Data: Commonwealth Fund Biennial Health Insurance Survey (2022).

Source: Sara R. Collins, Lauren A. Haynes, and Relebohile Masitha, *The State of U.S. Health Insurance in 2022: Findings from the Commonwealth Fund Biennial Health Insurance Survey* (Commonwealth Fund, Sept. 2022). <https://doi.org/10.26099/73zg-3432>



EMPLOYERS BRACE FOR 2024

THE WALL STREET JOURNAL

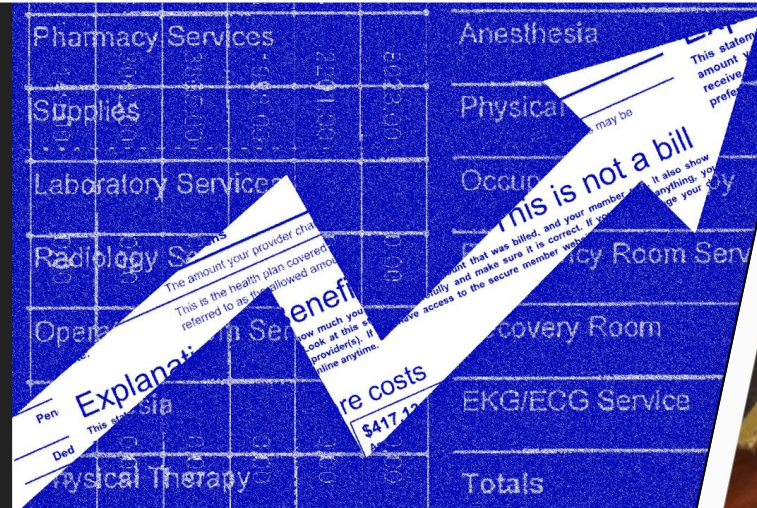
Limited Offer: 50¢/Week Sign In

SPECIAL OFFER

World Business U.S. Politics Economy Tech Finance Opinion Arts & Culture Lifestyle Real Estate Personal Finance Health Science Style Sports

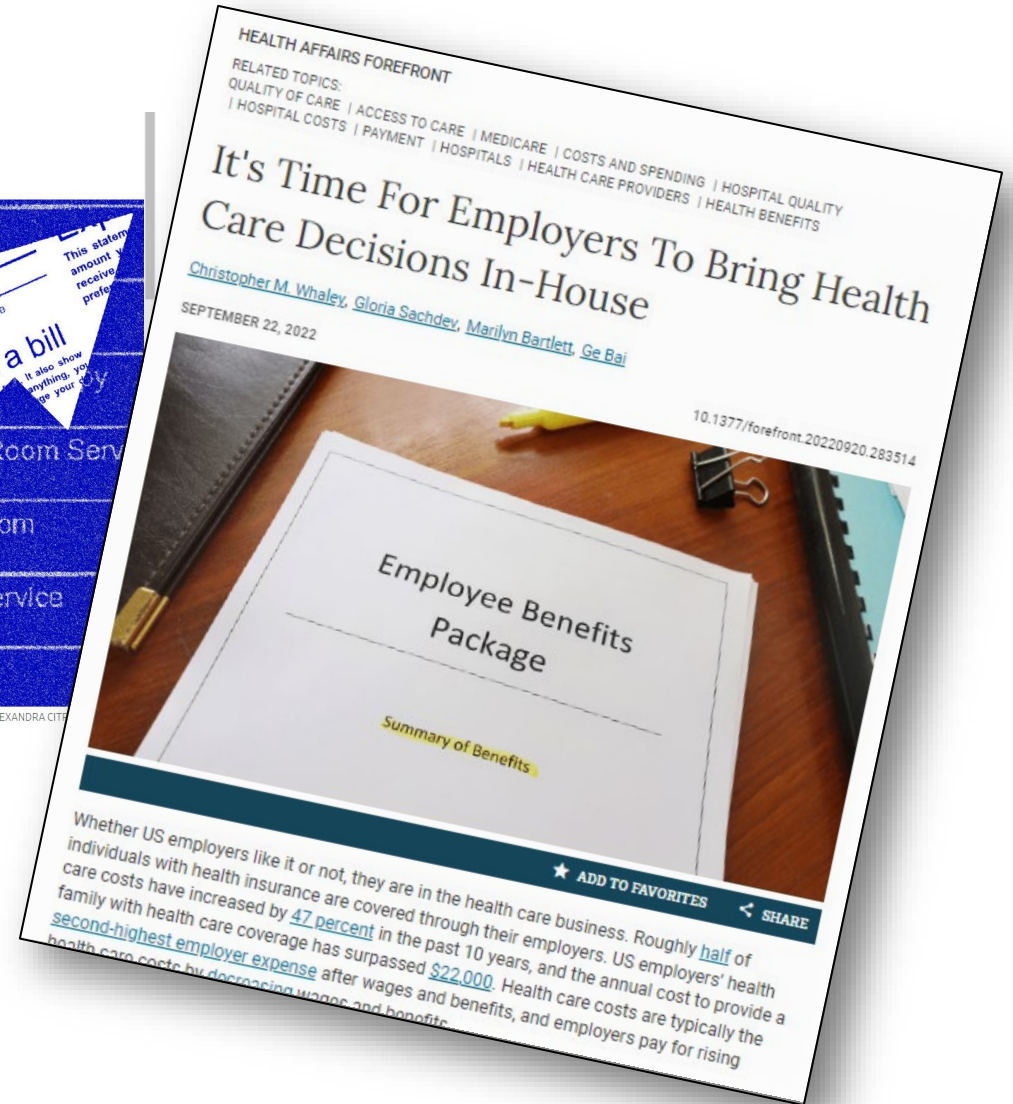
Health-Insurance Costs Are Taking Biggest Jumps in Years

Employers and workers are expected to see an increase of about 6.5% or higher in health-plan costs next year



“Large employers cannot continue to be the piggy bank for a broken system that is unwilling to meet the needs of its customers.”

– Elizabeth Mitchell, CEO, PBGH



Premiums Are Not The Only Cost!



State Individual Mandates
Are you affected?

[Not on the list? You could be soon...]



1095-C Employee-Provided Health Insurance Offer and Coverage

Employee: [Name] Applicable Large Employer Member (Employee): [Name]

Employer: [Name] Applicable Large Employer Member (Employer): [Name]

Employee Offer and Coverage

Month	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Employee												
Spouse												
Child												
Other												

Controlled Individuals

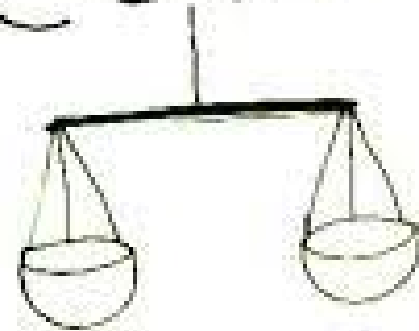
Month	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Individual 1												
Individual 2												
Individual 3												
Individual 4												
Individual 5												



RxDC Reporting Deadlines



OPPORTUNITY
COST



The Cost of Health Inequity

Burden by Racial & Ethnic Minority Groups

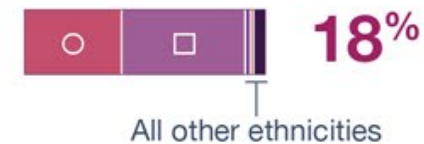
Black/African American ○	\$310B	69%
Hispanic/Latino □	\$94B	21%
American Indian/Alaska Native ⌘	\$26B	6%
Native Hawaiian/Pacific Islander ◇	\$12B	3%
Asian △	\$8B	2%

Burden by Economic Components and Racial & Ethnic Minority Groups

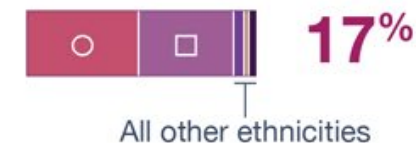
Excess Premature Deaths \$293B



Lost Labor Market Productivity \$81B



Excess Medical Care Costs \$77B



So, what can we do?



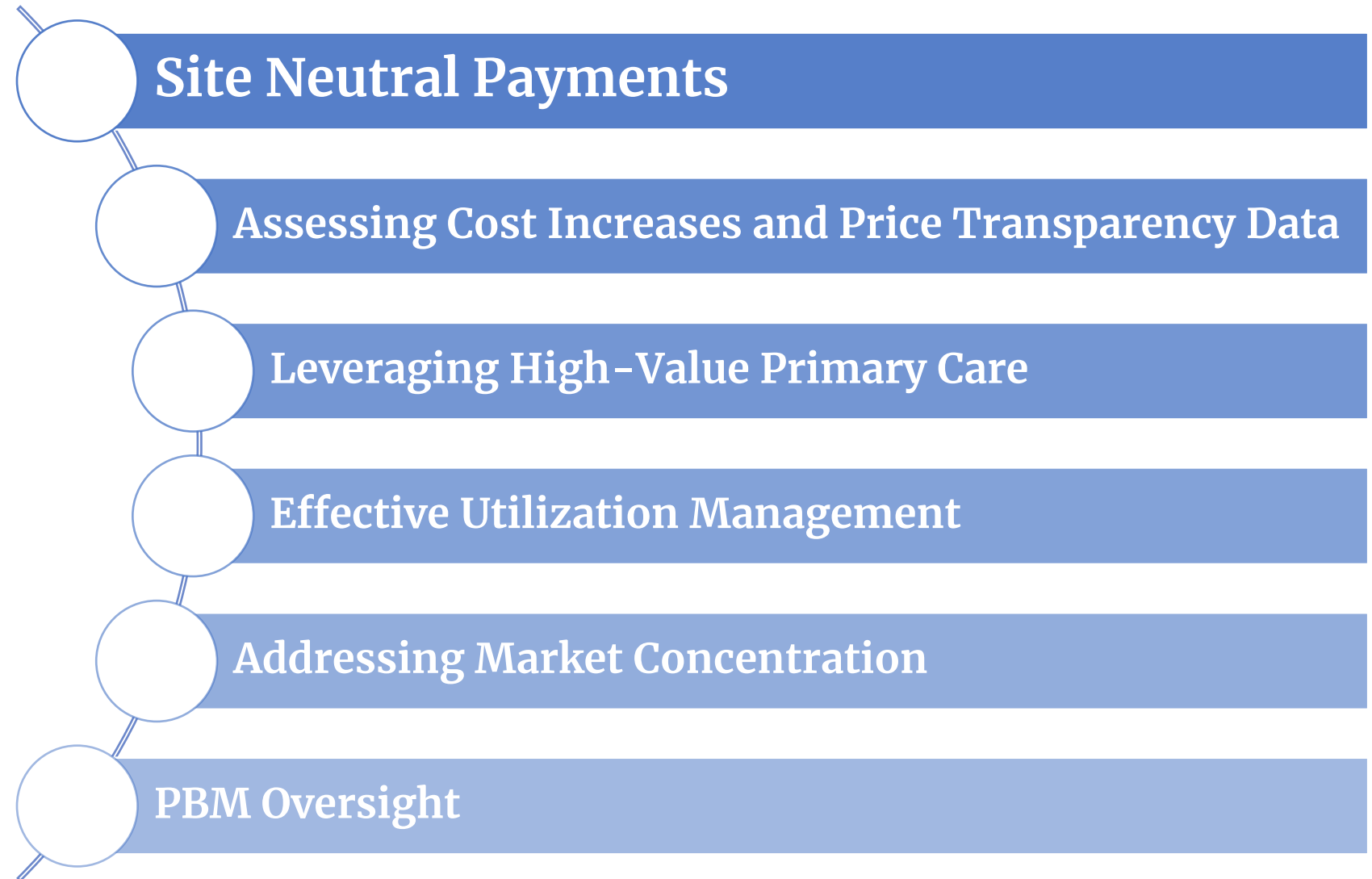
Some Ideas...

Identify the
true cost
drivers

Give attention
to the plight of
the
underinsured

Focus on Social
Determinants
of Health

A few others...





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Questions?