

Revised: 8/4/22

2022 Summer National Meeting
Portland, Oregon

REGULATORY FRAMEWORK (B) TASK FORCE

Wednesday, August 10, 2022

11:30 a.m. – 1:00 p.m.

Oregon Convention Center—Portland Ballroom 252–253—Level 2

ROLL CALL

Vicki Schmidt, Chair	Kansas	Chris Nicolopoulos	New Hampshire
Sharon P. Clark, Vice Chair	Kentucky	Marlene Caride	New Jersey
Mark Fowler	Alabama	Russell Toal	New Mexico
Lori K. Wing-Heier	Alaska	Mike Causey	North Carolina
Peni Itula Sapini Teo	American Samoa	Jon Godfread	North Dakota
Ricardo Lara	California	Edward M. Deleon Guerrero	Northern Mariana Islands
Michael Conway	Colorado	Judith L. French	Ohio
Andrew N. Mais	Connecticut	Glen Mulready	Oklahoma
Trinidad Navarro	Delaware	Andrew R. Stolfi	Oregon
Karima M. Woods	District of Columbia	Michael Humphreys	Pennsylvania
David Altmaier	Florida	Patrick Tigue	Rhode Island
Dean L. Cameron	Idaho	Larry D. Deiter	South Dakota
Amy L. Beard	Indiana	Carter Lawrence	Tennessee
Doug Ommen	Iowa	Cassie Brown	Texas
Timothy N. Schott	Maine	Jon Pike	Utah
Gary D. Anderson	Massachusetts	Scott A. White	Virginia
Anita G. Fox	Michigan	Mike Kreidler	Washington
Grace Arnold	Minnesota	Allan McVey	West Virginia
Chlora Lindley-Myers	Missouri	Nathan Houdek	Wisconsin
Eric Dunning	Nebraska		

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

AGENDA

1. Consider Adoption of its Spring 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 Usage of the Term “Interchangeable Biosimilar Product” in the *Health Carrier Prescription Drug Benefit Management Model Act (#22)* and its Effect on Prescription Drug Substitutions—*Craig Burton (Association for Accessible Medicines—AAM)*
5. Hear an Update on the Implementation of the Federal Network Adequacy Standards for Qualified Health Plans (QHPs) in the Federally Facilitated Health Insurance Exchanges—*Brian R. Webb (NAIC)*
6. Discuss Any Other Matters Brought Before the Task Force—*Commissioner Vicki Schmidt (KS)*
7. Adjournment

Agenda Item #1

Consider Adoption of its Spring National Meeting Minutes
—*Commissioner Vicki Schmidt (KS)*

Draft Pending Adoption

Draft: 4/13/22

Regulatory Framework (B) Task Force
Virtual Meeting (*in lieu of meeting at the 2022 Spring National Meeting*)
March 23, 2022

The Regulatory Framework (B) Task Force met March 23, 2022. The following Task Force members participated: Vicki Schmidt, Chair (KS); Sharon P. Clark, Vice Chair (KY); Lori K. Wing-Heier represented by Sarah Bailey (AK); Jim L. Ridling represented by Anthony L. Williams, William Rodgers, and Yada Horace (AL); Evan G. Daniels represented by Erin Klug (AZ); Ricardo Lara represented by Tyler McKinney and Wendy Hill (CA); Michael Conway represented by Kate Harris and Debra Judy (CO); Andrew N. Mais represented by Jared Kosky and Paul Lombardo (CT); Karima M. Woods represented by Howard Liebers (DC); Trinidad Navarro represented by Susan Jennette (DE); David Altmaier represented by Chris Struk and James Dunn III (FL); Doug Ommen (IA); Dean L. Cameron represented by Kathy McGill (ID); Amy L. Beard represented by Alex Peck and Cory Best (IN); Gary D. Anderson represented by Kevin Beagan (MA); Eric A. Cioppa represented by Robert Wake (ME); Anita G. Fox represented by Renee Campbell, Chad Arnold, and Karen Dennis (MI); Grace Arnold represented by Galen Benshoof and Sherri Mortensen-Brown (MN); Chlora Lindley-Myers (MO); Mike Causey represented by Ted Hamby and Robert Croom (NC); Jon Godfread represented by Chrystal Bartuska (ND); Eric Dunning and Laura Arp (NE); Chris Nicolopoulos represented by Michelle Heaton and Jason Dexter (NH); Marlene Caride represented by Chanell McDevitt (NJ); Russell Toal (NM); Judith L. French represented by Laura Miller and Marjorie Ellis (OH); Glen Mulready represented by Andrew Schallhorn (OK); Andrew R. Stolfi represented by Jesse O'Brien (OR); Michael Humphreys (PA); Patrick Tighe represented by Patrick Smock (RI); Larry D. Deiter represented by Jill Kruger and Candy Holbrook (SD); Carter Lawrence represented by Scott McAnally (TN); Cassie Brown represented by Rachel Bowden (TX); Jon Pike represented by Shelley Wiseman and Heidi Clausen (UT); Scott A. White represented by Julie Blauvelt, Bob Grissom, Bradley Marsh, and James Young (VA); Mike Kreidler represented by Molly Nollette and Jane Beyer (WA); Nathan Houdek (WI); and Allan L. McVey (WV). Also, participating was: Erica Weyhenmeyer (IL).

1. Adopted its 2021 Fall National Meeting Minutes

Commissioner Clark made a motion, seconded by Ms. Kruger, to adopt the Task Force's Nov. 30, 2021, minutes (*see NAIC Proceedings – Fall 2021, Regulatory Framework (B) Task Force*). The motion passed unanimously.

2. Adopted its Subgroup and Working Group Reports

a. Accident and Sickness Insurance Minimum Standards (B) Subgroup

Ms. Arp said the Subgroup met March 21, March 7, Feb. 14, 2022, and Dec. 6, 2021. She said that during these meetings, the Subgroup continued its discussion of revisions to Sections 1–7 of the *Model Regulation to Implement the Accident and Sickness Insurance Minimum Standards Model Act (#171)* based on the comments received by the July 2, 2021, public comment deadline. The Subgroup also 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.

Ms. Arp said the Subgroup devoted most of its discussion during its March meetings on how to address indemnity products in Model #171 given the different plan designs for this product, differing state approaches to regulating this product, and complex federal law and regulations related to this product. She said the Subgroup requested comments, including redline language, to revise Section 7B—Hospital Indemnity or Other Fixed Indemnity Coverage to address the issues raised during the Subgroup's discussions. She said any comments received will be discussed during the Subgroup's April 18 meeting.

Draft Pending Adoption

Ms. Arp said that in an effort to educate stakeholders on the types of products to be regulated under Model #171, the Subgroup has also had extensive discussions on these types of products, their purpose, how they are marketed, and how they are sold. She said she anticipates a significant amount of the Subgroup's work will be focused on adding provisions to Model #171 regulating STLD plans. She said this work will be extensive because of the product's characteristics and the lack of existing language in Model #171 regulating it.

Ms. Arp said the Subgroup's goal is to finish its work revising Model #171 by the end of the year and forward the revised model to the Task Force for its consideration.

b. ERISA (B) Working Group

Mr. Wake said the Employee Retirement Income Security Act (ERISA) (B) Working Group met March 22. During this meeting, the Working Group exposed a revised draft case summary of *Rutledge v. Pharmaceutical Care Management Association (PCMA)* for inclusion in the *Health and Welfare Plans Under the Employee Retirement Income Security Act: Guidelines for State and Federal Regulation* (ERISA Handbook) for a 30-day public comment period ending April 21. The Working Group also discussed potential updates and issues to consider for inclusion in the ERISA Handbook. Mr. Wake said the Working Group adjourned into regulator-to-regulator session, pursuant to paragraph 2 (pending investigations which may involve either the NAIC or any member in any capacity), paragraph 3 (specific companies, entities or individuals), paragraph 8 (consideration of strategic planning issues), and paragraph 9 (any other subject required to be kept confidential) of the NAIC Policy Statement on Open Meetings.

Superintendent Toal asked if the Working Group will be able to come to some consensus related to the regulation of pharmacy benefit managers (PBMs) and ERISA preemption because New Mexico and most likely other states are looking for some direction with respect to their regulatory authority. Mr. Wake said he believes that some of these issues are within the purview of the Pharmacy Benefit Manager Regulatory Issues (B) Subgroup. He said he believes the Working Group will be able to state what is the law at this point. He noted that many of the issues related to ERISA preemption are still being litigated with the federal circuit courts taking different approaches. He said that when a case does not involve insurance, the Working Group does not have a "right" or "wrong" view. Mr. Wake said that the recent wave of state laws regulating PBMs do not really involve insurance regulation, but the states have deliberately decided for public policy reasons that such regulation is important and to the extent federal law allows it, they want to regulate PBMs and the field of pharmacy benefits even if such regulation falls outside of the insurance regulatory sphere.

c. MHPAEA (B) Working Group

Ms. Weyhenmeyer said most of the Mental Health Parity and Addiction Equity Act (MHPAEA) (B) Working Group meetings to date have been in regulator-to-regulator session to provide the opportunity for Working Group members and interested state insurance regulators to discuss MHPAEA enforcement and compliance issues, including its last meeting on March 1. She said that during its March 1 meeting, the Working Group discussed potential changes to the mental health parity chapter of the *Market Regulation Handbook*. She explained that the Working Group will review the chapter and forward any suggested revisions to the Market Conduct Examination Guidelines (D) Working Group for its consideration. She explained that stakeholders will have the opportunity to comment on any suggested changes to the mental health parity chapter during the Market Conduct Examination Guidelines (D) Working Group's discussions of the revisions.

Ms. Weyhenmeyer said that during its March 1 meeting, the Working Group also discussed potential agenda items for its April 5 meeting at the Spring National Meeting. She said the Working Group plans to hold an open session during which it plans to hear: 1) a presentation from Illinois and Washington on a designation in behavioral health parity analysis under development by the Insurance Regulatory Examiners Society (IRES); 2) a presentation from

Draft Pending Adoption

the U.S. Department of Labor (DOL) on mental health parity enforcement activities; and 3) a presentation from the American Psychiatric Association (APA) outlining an example of how insurers may document compliance with mental health parity regulations. She said that following its open session, the Working Group would adjourn into regulator-to-regulator session pursuant to paragraph 3 (specific companies, entities or individuals), paragraph 8 (consideration of strategic planning issues), and paragraph 9 (any other subject required to be kept confidential) of the NAIC Policy Statement on Open Meetings.

d. Pharmacy Benefit Manager Regulatory Issues (B) Subgroup

Ms. Arp said the Pharmacy Benefit Manager Regulatory Issues (B) Subgroup met March 16. During this meeting, the Subgroup adopted its 2021 Fall National Meeting minutes. The Subgroup also heard a presentation from the Montana Department of Insurance (DOI) on its PBM law and implementation. NAIC staff provided an update on their work to compile state PBM laws and regulations regulating PBM business practices.

Ms. Arp said that during its April 4 meeting at the Spring National Meeting, the Subgroup plans to hear an update from the Oklahoma DOI on its PBM law and implementation, as well as suggestions on best practices and lessons learned. The Subgroup also will hear from Oregon on PBM regulation and beyond, including its efforts related to prescription drug transparency and affordability. She said the Subgroup welcomes additional presentations from the states on an ongoing basis on what they are doing with respect to PBM regulation consistent with the Subgroup's 2022 charge. She said the Subgroup also will hear from the NAIC consumer representatives. They will provide a consumer perspective on the Subgroup's 2022 charge to develop a white paper on PBM business practices, including a discussion on the impact the *Rutledge* decision has, if any, on state regulation PBM business practices.

Ms. Arp said that with respect to the Subgroup's future meetings, the Subgroup conducted a survey of its members early this year to gain information on which speakers would be most helpful for the Subgroup to hear from in terms of background presentations on PBM regulation. She also noted that the Subgroup's 2022 charge is broader than PBM regulation. As a result, the Subgroup will need to broaden its discussion to get a better understanding of the entire prescription drug supply chain. She said one of the Subgroup's first speakers will be Dr. Neeraj Sood from the University of Southern California (USC), who will present in April on his latest work on prescription drug pricing and supply chain economics. The Subgroup plans to receive background presentations throughout the period before the Summer National Meeting.

Ms. Arp said the Subgroup hopes to begin writing the white paper after it completes its background presentations. She said the Subgroup will establish small ad hoc groups to work on specific issues and/or components of the paper with a goal of completing its work by the Fall National Meeting. She said the Subgroup knows there is a lot of interest in PBM regulation, particularly state activities related to PBM regulation. The Subgroup is compiling information it receives from the states and posting it on the Subgroup's web page. Ms. Arp explained that because an analysis of the *Rutledge* decision is part of its 2022 charge to develop a white paper, the Subgroup will rely on the expertise of the ERISA (B) Working Group and await its analysis of the decision to incorporate in the white paper.

Commissioner Clark suggested that the Subgroup provide notice of its upcoming meetings to all state insurance regulators. Ms. Arp agreed to work with NAIC staff to ensure that notice of the Subgroup meetings, including specific planned speakers and presentations, is provided.

Commissioner Schmidt requested that the states send information to the Subgroup and NAIC staff on their PBM laws, including those recently enacted during just concluded legislative sessions. She said the Subgroup is compiling these laws as a resource for the states, and it is important that it is as accurate and up to date as possible because stakeholders are looking at it.

Draft Pending Adoption

Commissioner Clark made a motion, seconded by Ms. Nollette, to adopt the following reports: the Accident and Sickness Insurance Minimum Standards (B) Subgroup, including its March 21, 2022 (Attachment One), March 7, 2022 (Attachment Two), Feb. 14, 2022 (Attachment Three), and Dec. 6, 2021, (Attachment Four) minutes; the ERISA (B) Working Group, including its March 22 minutes (Attachment Five); the MHPAEA (B) Working Group; and the Pharmacy Benefit Manager Regulatory Issues (B) Subgroup, including its March 16 minutes (Attachment Six). The motion passed unanimously.

3. Heard an Update on the CHIR's Work

Maanasa Kona (Center on Health Insurance Reforms—CHIR, Georgetown University Health Policy Institute) provided an update on the CHIR's recent and forthcoming work. She highlighted the work the CHIR has been doing related to the implementation of the federal No Surprises Act (NSA). Ms. Kona said that because the NSA does not include provisions related to surprise bills for ground ambulance services, the CHIR decided that it was important to understand what the states have done in this area. She said the CHIR compiled information on state protections for ground ambulance surprise bills to provide such a resource. She said the CHIR has a new interactive map on the roles of federal and state officials on various aspects of the NSA—issuer enforcement, provider enforcement, and the interaction between federal and state balance billing laws. She said the interactive map can be found on the Commonwealth Fund's website. Ms. Kona said the CHIR expects to soon publish an issue brief based on interviews with 12 state DOIs on their approaches to NSA implementation.

Ms. Kona said the CHIR is continuing its work related to the COVID-19 public health emergency (PHE), including research on state preparations for the end of the PHE based on interviews with Medicaid and state-based marketplace (SBM) officials from 11 states. She said other work the CHIR is doing related to the COVID-19 PHE includes examining the lack of compliance with COVID-19 testing coverage mandates and studying the impact of COVID-19 on small business health insurance.

Ms. Kona said the CHIR is also continuing to examine issues with alternative types of noncompliant federal Affordable Care Act (ACA) coverage. One such issue is the misleading marketing of such plans during the COVID-19 Special Enrollment Period (SEP). She noted that data from Massachusetts on health care sharing ministries (HCSMs) revealed that their finances put consumers at risk. She said the CHIR recently released an issue brief on state "easy enrollment" programs, which found that such programs have gained momentum and potentially lay the groundwork for additional efforts to expand coverage. The CHIR plans *CHIRblog* posts on SBM outreach and advertising efforts during the most recent Open Enrollment Period (OEP). She said the CHIR is also planning a state spotlight on California's *CHIRblog* post.

Ms. Kona said the CHIR has released other issue briefs of potential interest and reading, including issue briefs on 1) leveraging the new federal health care transparency rules to contain costs; and 2) network adequacy standards and oversight. She said upcoming issue briefs and *CHIRblog* posts include comparing network adequacy rules across marketplaces and Medicaid managed care organizations (MCOs), state efforts to improve federal MHPAEA compliance; and SBM efforts to improve health equity.

3. Heard a Discussion on the HSA, HDHP, and Prescription Drug Copayment Accumulator Issue

Carl Schmid (HIV + Hepatitis Policy Institute) and Jeffrey Klein and Roy Ramthun (American Bankers Association [ABA] Health Savings Account [HSA] Council) discussed the HSA, high-deductible health plan (HDHP), and prescription drug copayment accumulator issue.

The discussion highlighted the importance of prescription copayment assistance to consumers and its role in helping to reduce out-of-pocket costs. The speakers discussed: 1) the percentage of plans in states with

Draft Pending Adoption

copayment accumulator policies and states with laws banning copayment accumulators; 2) potential conflicts of state copayment accumulator ban laws with federal requirements related to HSA-qualified HDHP and continued eligibility to contribute to an HSA in light of such a law; and 3) potential solutions and options to address this issue, including a suggestion that the Task Force consider developing a model bulletin that state DOIs can use to educate consumers on the issue. The speakers also suggested model language for those states that may be contemplating enacting legislation banning copayment accumulator use as a carve-out for HSA-qualified HDHP plans to address any potential conflict with federal HSA-qualified HDHP requirements.

Kris Hathaway (America's Health Insurance Plans—AHIP) said AHIP submitted a comment letter to the Task Force on two issues it believes affects many health care consumers and purchasers: 1) copayment coupons, which AHIP believes increase costs for consumers for drug manufacturers' own financial gain; and 2) HSA-qualified HDHP eligibility to contribute to an HSA in light of state laws banning copayment accumulators. She acknowledged the Task Force's current discussion of the second issue during this meeting. She said AHIP urges the Task Force to consider taking additional action following this meeting to address this issue, including: 1) raising this issue with the federal agencies charged with implementing the HSA Internal Revenue Service (IRS) law and requesting updated clarifying guidance; 2) educating state 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; and 3) in states that have passed laws, supporting new legislation to exempt HSAs from these laws.

With respect to the issue of copayment coupons, Ms. Hathaway said AHIP recommends that the Pharmacy Benefit Manager Regulatory Issues (B) Subgroup include the issue of coupons as part of its white paper because it is an issue of critical importance to premiums for a state's entire population. The paper should include information that enlists a better understanding of the market and the impact of copayment coupons, as well as offer specific guardrails that protect consumers equally.

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

SharePoint/NAIC Support Staff Hub/Member Meetings/2022 NAIC Meetings/Spring National Meeting/Committee Meetings/HEALTH INS and MANAGED CARE (B) COMMITTEE/Reg Framework (B) TF/RFTF 3-23-22 MtgMin.docx

Agenda Item #2

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

- ***Accident and Sickness Insurance Minimum Standards (B) Subgroup—Laura Arp (NE) and Andy Schallhorn (OK)***
- ***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**

July 11, 2022 / June 13, 2022 / June 6, 2022 / May 9, 2022 / April 18, 2022

Summary Report

The Accident and Sickness Insurance Minimum Standards (B) Subgroup of the Regulatory Framework (B) Task Force met July 11, June 13, June 6, May 9, and April 18, 2022. During these meetings, the Subgroup:

1. Discussed comments received on Section 8B—Hospital Indemnity or Other Fixed Indemnity Coverage of the *Model Regulation to Implement the Accident and Sickness Insurance Minimum Standards Model Act (#171)* and its drafting note to clarify what is and what is not “fixed indemnity coverage.”
2. Based on the comments received and discussion, developed a chair draft of proposed revisions to Section 8B.
3. Discussed the chair draft of proposed revisions to Section 8B and agreed on preliminary revisions to Section 8B for inclusion in the draft of revisions to Model #171.
4. Discussed comments received on the NAIC consumer representatives’ initial comments on Section 8C-Disability Income Protection Coverage and agreed on preliminary revisions to Section 8C for inclusion in the draft of revisions to Model #171.

Draft: 7/18/22

Accident and Sickness Insurance Minimum Standards (B) Subgroup
Virtual Meeting
July 11, 2022

The Accident and Sickness Insurance Minimum Standards (B) Subgroup of the Regulatory Framework (B) Task Force met July 11, 2022. The following Subgroup members participated: Laura Arp, Co-Chair (NE); Andy Schallhorn, Co-Chair (OK); Debra Judy (CO); Chris Struk (FL); Amy Hoyt and Camille Anderson-Weddle (MO); Shari Miles (SC); Rachel Bowden (TX); Shelley Wiseman, Heidi Clausen, and Tanji J. Northrup (UT); Jamie Gile and Mary Block (VT); and Ned Gaines (WA).

1. Continued Discussion of Suggested Revisions to Section 8C of Model #171

The Subgroup continued its discussion from its June 13 meeting of the comments received on the NAIC consumer representatives' initial comments on Section 8C—Disability Income Protection Coverage of the *Model Regulation to Implement the Accident and Sickness Insurance Minimum Standards Model Act (#171)*. Ms. Arp asked for additional discussion on Section 8C(1) concerning the age an insurer could potentially reduce periodic payments based solely on age and the NAIC consumer representatives' concern that this provision could encourage an individual to take early retirement at age 62 with reduced Social Security benefits. Their suggestion is to revise this provision to require that any reduction in benefits related to a person's age be tied to an individual's eligibility for full Social Security retirement benefits, not their eligibility for early retirement benefits.

Chris Petersen (Arbor Strategies) said America's Health Insurance Plans (AHIP) has no issues with the current language in Section 8C(1), but in the interest of addressing the NAIC consumer representatives' concerns, AHIP could support removing Section 8C(1) altogether. J.P. Wieske (Health Benefits Institute—HBI) said that it is HBI's understanding that this provision is rarely, if at all, used because it is hard to administer. Anna Schwamlein Howard (American Cancer Society Cancer Action Network—ACS CAN) asked about the impact of removing Section 8C(1) and whether due to its removal, insurers could reduce benefits at any age. The Subgroup discussed the interaction of Section 8C(1) with Section 8C(3). Ms. Howard suggested adding language to Section 8C(1) to refer to both "Social Security retirement benefits" and "Social Security disability income benefits." Mr. Wieske expressed concern with adding such language because Section 8C(1) only concerns Social Security retirement benefits. The Subgroup discussed using the term "Social Security normal retirement age (SSNRA)," as referenced in the HBI's comments. The Subgroup discussed various revisions to Section 8C(1). After additional discussion, the Subgroup decided to revise Section 8C(1) based on the NAIC consumer representatives' suggested revisions.

The Subgroup next discussed Section 8C(2). Ms. Howard reiterated the NAIC consumer representatives' concerns with the elimination periods. After discussion, the Subgroup decided to leave the provision unchanged.

The Subgroup next discussed Section 8C(3). After discussion, the Subgroup decided to remove the phrase referring to pregnancy, childbirth, or miscarriage. During its May 9 meeting, the Subgroup had agreed to change the reference to six months to three months. The Subgroup next discussed Section 8C(4). Ms. Howard pointed out the NAIC consumer representatives' suggestion to add the word "both" for clarity. After discussion, the Subgroup agreed to accept the suggested revision.

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 7-11-22MtgMin.docx

Draft: 6/23/22

Accident and Sickness Insurance Minimum Standards (B) Subgroup
Virtual Meeting
June 13, 2022

The Accident and Sickness Insurance Minimum Standards (B) Subgroup of the Regulatory Framework (B) Task Force met June 13, 2022. The following Subgroup members participated: Laura Arp, Co-Chair (NE); Andy Schallhorn, Co-Chair (OK); Howard Liebers (DC); Chris Struk (FL); Robert Wake (ME); Amy Hoyt (MO); Rachel Bowden (TX); Shelley Wiseman, Heidi Clausen, and Tanji J. Northrup (UT); Anna Van Fleet, Mary Block, Emily Brown, Jamie Gile, and Christine Menard-O'Neil (VT); and Ned Gaines (WA).

1. Continued Discussion of Suggested Revisions to Section 8B of Model #171

Using the NAIC staff comment chart (see NAIC Proceedings – Summer 2022, Regulatory Framework (B) Task Force, Attachment ?-A), the Subgroup continued its discussion from its June 6 meeting of the comments received on the co-chair's draft proposed revisions to Section 8B—Hospital Indemnity or Other Fixed Indemnity Coverage of the *Model Regulation to Implement the Accident and Sickness Insurance Minimum Standards Model Act* (#171) and its drafting note. Jolie H. Matthews (NAIC) pointed out draft language for a proposed drafting note for Section 8B(2). She said this proposed drafting note is intended to address the Subgroup's June 6 meeting discussion about the placeholder language. After discussion, the Subgroup agreed to add the proposed drafting note to the draft of proposed revisions to Model #171. Mr. Struk suggested adding the word "minimum" before the words "benefit amounts." The Subgroup accepted his suggested revision.

The Subgroup next discussed the Law Office of William G. Schiffbauer comments suggesting revisions to the drafting notes. Ms. Arp said she believes the suggested language for the drafting note is a good reminder to state insurance regulators that it is not necessarily the product that is the issue, but how some insurance producers and insurers market and sell the product to consumers, leading the consumer to believe it is a substitute for major medical insurance coverage. The Subgroup discussed the suggested language. After discussion, the Subgroup agreed to add the language. The Subgroup also agreed to accept the American Council of Life Insurers' (ACLI's) suggested edit to Section 8B(1) to change "benefit" to "benefits" and change "event" to "events."

2. Discussed Comments Received on Section 8C of Model #171

The Subgroup next discussed the comments received on the NAIC consumer representatives' initial comments on Section 8C—Disability Income Protection Coverage. Ms. Arp said NAIC staff compiled a chart reflecting the comments received from the ACLI, America's Health Insurance Plans (AHIP), the Health Benefits Institute (HBI), and the NAIC consumer representatives (Attachment ?-A). The Subgroup discussed the comments on Section 8C(1) concerning the age an insurer could potentially reduce periodic payments based solely on age. Cindy Goff (ACLI) discussed the ACLI's comments and the need for flexibility when an individual elects to receive Social Security benefits at age 62; as a result, the part of the individual's income is being replaced by those benefits. She explained that this is optional for the insurer, not a requirement. The Subgroup discussed the NAIC consumer representatives' concern that this provision could encourage an individual to take early retirement at age 62 with reduced Social Security benefits, and their suggestion is to revise this provision to require that any reduction in benefits related to a person's age be tied to an individual's eligibility for full Social Security retirement benefits, not their eligibility for early retirement benefits. Ms. Goff explained that this provision does not require an insurer to automatically reduce benefits when an individual turns age 62. The provision allows the insurer, if the insurer decides to do so, to reduce the benefit when the individual elects to take early retirement and access Social Security retirement benefits at age 62. Anna Schwamlein Howard (American Cancer Society, Cancer Action

Network—ACS CAN) asked if Ms. Goff could confirm her comments and understanding on how this provision works with her colleagues at the ACLI during a future Subgroup meeting. Ms. Goff agreed.

Ms. Arp asked about the last sentence in Section 8C(3), which states, “No reduction in benefits shall be put into effect because of an increase in Social Security or similar benefits during a benefit period.” Ms. Howard said she believes this language refers to Social Security disability benefits, not Social Security retirement benefits. Bonnie Burns (California Health Advocates—CHA) pointed out that the reference in Section 8C(3) to Social Security does not specifically state whether it is Social Security disability benefits or Social Security retirement benefits. She also expressed concern that an insurer could include a provision in a disability income protection policy requiring an insured to elect early Social Security retirement benefits at age 62. Mr. Schallhorn said he believes this provision was included to establish a floor as to how much an insurer can reduce benefits based solely on age if the insurer elects to reduce the benefits. He said without this provision, an insurer could potentially reduce the amount of benefits at its discretion at age 62. Ms. Howard explained that to address its concerns with this provision, the NAIC consumer representatives suggest tying the reduction of benefits to when an individual reaches full Social Security retirement age. Ms. Arp said the HBI suggests similar language in its comments. She also pointed out that in its comments, AHIP says it could support revising the specific age of 62 to a more flexible reference, such as “the Social Security retirement age.” The Subgroup discussed these comments, including that “full” Social Security retirement age differs based on when an individual was born.

Ms. Arp asked Ms. Goff to poll her colleagues at the ACLI and ACLI members on whether the reference to and language related to age 62 in Section 8C(1) is tied to Social Security retirement benefits or refers to something else. Ms. Goff also agreed to try to get clarification on the language in Section 8C(3) referring to “benefit period” and the length of such a period, such as whether it is a month, a year, or the length of the claim.

Chris Petersen (Arbor Strategies LLC) said AHIP suggests revising Section 3—Applicability and Scope to include a reference to “certificate” to reflect that Model #171 now applies to group disability income protection policies. The Subgroup took this suggested revision under advisement.

The Subgroup decided to continue this discussion during its next meeting on July 11.

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

SharePoint/NAIC Support Staff Hub/Member Meetings/2022 NAIC Meetings/Summer National Meeting/Committee Meetings/HEALTH INS and MANAGED CARE (B) COMMITTEE/Reg Framework (B) TF/Accident and Sickness (B) Subgroup/Accident and Sickness Ins Min Stds Subgrp 6-13-22MtgMin.docx

Draft: 6/14/22

Accident and Sickness Insurance Minimum Standards (B) Subgroup
Virtual Meeting
June 6, 2022

The Accident and Sickness Insurance Minimum Standards (B) Subgroup of the Regulatory Framework (B) Task Force met June 6, 2022. The following Subgroup members participated: Laura Arp, Co-Chair (NE); Andy Schallhorn, Co-Chair (OK); Chris Struk (FL); Camille Anderson-Weddle, Amy Hoyt, and Cynthia Amann (MO); Shari Miles (SC); Rachel Bowden (TX); Shelley Wiseman and Tanji J. Northrup (UT); Anna Van Fleet, Mary Block, and Jamie Gile (VT); and Ned Gaines (WA).

1. Discussed Suggested Revisions to Section 8B of Model #171

Ms. Arp said in response to the Subgroup's request for comments on the co-chair's draft proposed revisions to Section 8B—Hospital Indemnity or Other Fixed Indemnity Coverage of the *Model Regulation to Implement the Accident and Sickness Insurance Minimum Standards Model Act (#171)* and its drafting note, the Subgroup received comments from the American Council of Life Insurance (ACLI), America's Health Insurance Plans (AHIP), the Health Benefits Institute (HBI), the NAIC consumer representatives, the Law of Office William G. Schiffbauer (Schiffbauer), and the Vermont Department of Insurance (DOI). She said NAIC staff developed a chart reflecting the comments received, including suggested revisions to the co-chair's draft proposed revisions (Attachment ?-A). Each of the commenters discussed their comments.

With respect to the ACLI's suggestion to add "fixed percentage," the Subgroup decided not to accept the suggested revision because such language could be confusing to consumers. In addition, the Subgroup said adding such language would deviate from the federal definition with respect to indemnity products. The Subgroup discussed the general purpose of the co-chair's proposed revisions to this provision, including the drafting notes, which is to provide guidance to state insurance regulators on the framework for these products and provide some guardrails on what products fall within the provision's scope and those products that do not.

The Subgroup discussed AHIP's suggestion to replace "health-related" event with "specified" event. Ms. Arp asked if there would ever not be a "health-related" event. After discussion, the Subgroup decided not to accept the suggested revision because of how benefits are triggered. Benefits are triggered based on a health-related event, but the benefits provided due to that triggering event may not be "health-related." To address these issues, the Subgroup decided to revise the language to add "triggered by."

The Subgroup discussed Schiffbauer's comments, including whether the language should include the specific reference to the federal law on excepted benefits and the differences in the language in federal law for individual coverage versus group coverage. After discussion, the Subgroup decided to remove the reference and consider adding language to the last drafting note to flag it for state insurance regulators when reviewing form filings. The Subgroup discussed the following language for the potential drafting note: "If the product does not meet the federal definition of excepted benefits under 42 U.S.C. §300gg 91(c)(3) and its implementing regulations, it should be treated and regulated as a comprehensive major medical coverage subject to the requirements of the federal Affordable Care Act (ACA)."

The Subgroup discussed the HBI's suggestion to delete the reference to "31 days" in paragraph 2 and replace it with "[X] days" because "31 days" is outdated and possibly reflects the previous version of Model #171 that included major medical type coverage. The Subgroup discussed deleting paragraph 2. After additional discussion, the Subgroup decided to retain it because it exists in current state laws and regulations. To address concerns with

the placeholder language, the Subgroup decided to add a drafting note alerting state insurance regulators that when setting lump sum benefits or daily benefits for hospital indemnity coverage, they should be mindful to not set benefits that are so low that they may not provide any actual benefit to consumers or set benefits so high that consumers could be led to believe the coverage is major medical coverage.

The Subgroup decided to continue the discussion during its next meeting June 13.

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 6-6-22MtgMin.docx

Draft: 5/23/22

Accident and Sickness Insurance Minimum Standards (B) Subgroup
Virtual Meeting
May 9, 2022

The Accident and Sickness Insurance Minimum Standards (B) Subgroup of the Regulatory Framework (B) Task Force met May 9, 2022. The following Subgroup members participated: Laura Arp, Co-Chair (NE); Andy Schallhorn, Co-Chair (OK); Chris Struk (FL); Robert Wake (ME); Shari Miles (SC); Rachel Bowden (TX); Shelley Wiseman and Heidi Clausen (UT); Anna Van Fleet, Mary Block, Emily Brown, and Christine Menard-O'Neil (VT); and Ned Gaines (WA).

1. Continued Discussion of Comments Received on Model #171

Ms. Arp said that instead of reviewing a chair draft of proposed revisions to Section 8B—Hospital Indemnity or Other Fixed Indemnity Coverage of the *Model Regulation to Implement the Accident and Sickness Insurance Minimum Standards Model Act* (#171) and its drafting note reflecting the Subgroup's discussion during its April 18 meeting, the Subgroup would continue discussion of the comments received on Model #171 beginning with Section 8C—Disability Income Protection Coverage.

The Subgroup discussed America's Health Insurance Plans' (AHIP) suggestion to revise the length of the maximum period for which periodic payments are payable during a disability from at least six months to three months except in the case of a policy covering disability arising out of pregnancy, childbirth, or miscarriage. The Subgroup discussed the suggested revision. Some stakeholders expressed support for revising the time frame to permit more flexibility, particularly with respect to short-term disability income protection coverage. Ms. Arp expressed support for the revision. Without objection, the Subgroup accepted AHIP's suggested revision.

The Subgroup next discussed the NAIC consumer representatives' suggested revisions to Section 8C. Ms. Arp said the NAIC consumer representatives suggest striking the language in paragraph (1). For a policy providing periodic payments at ages after 62, paragraph (1) provides that an insurer may reduce such payments solely based on age at an amount at least 50% of amounts payable immediately prior to age 62. She said the NAIC consumer representatives also suggest shortening the elimination period time frames in paragraph (2). The NAIC consumer representatives also suggest lengthening the maximum period for a disability arising out of pregnancy, childbirth, or miscarriage from one month to three months in paragraph (3). The Subgroup discussed the suggested revisions. The Subgroup discussed why age 62 was chosen as the age when an insurer may reduce benefit payments. Some stakeholders suggested that age 62 was chosen because individuals can receive partial Social Security benefits at that age. The Subgroup also discussed the different elimination periods based on the length of benefit coverage. After discussion, the Subgroup decided to request comments on the NAIC consumer representatives' suggested revisions for a public comment period ending May 27. The Subgroup intends to review any comments received during its next meeting June 6. During its June 6 meeting, the Subgroup also plans to review comments submitted on the chair draft of proposed revisions to Section 8B.

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

SharePoint/NAIC Support Staff Hub/Member Meetings/2022 NAIC Meetings/Summer National Meeting/Committee Meetings/HEALTH INS and MANAGED CARE (B) COMMITTEE/Reg Framework (B) TF/Accident and Sickness (B) Subgroup/Accident and Sickness Ins Min Stds Subgrp 5-9-22MtgMin.docx

Draft: 5/9/22

Accident and Sickness Insurance Minimum Standards (B) Subgroup
Virtual Meeting
April 18, 2022

The Accident and Sickness Insurance Minimum Standards (B) Subgroup of the Regulatory Framework (B) Task Force met April 18, 2022. The following Subgroup members participated: Laura Arp, Co-Chair (NE); Andy Schallhorn, Co-Chair (OK); Debra Judy (CO); Chris Struk (FL); Amy Hoyt, Carrie Couch, and Cynthia Amann (MO); Shari Miles (SC); Rachel Bowden (TX); Shelley Wiseman and Heidi Clausen (UT); Jamie Gile and Christine Menard-O'Neil (VT); and Ned Gaines (WA).

1. Discussed Comments Received on Revising Section 8B of Model #171

Ms. Arp said that during the Subgroup's March 21 meeting, she asked Subgroup members, interested state insurance regulators, and interested parties to submit language for the Subgroup's consideration and discuss revisions to Section 8B—Hospital Indemnity or Other Fixed Indemnity Coverage of the *Model Regulation to Implement the Accident and Sickness Insurance Minimum Standards Model Act (#171)* and its drafting note clarifying what is and what is not "fixed indemnity coverage." She said the Subgroup received two comment letters—the Health Benefits Institute (HBI) and the Law Office of William G. Schiffbauer (Schiffbauer Law Office).

J.P. Wieske (HBI) said that in HBI's comments, it suggests adding a new drafting note to Section 8B that addresses the different approaches the states have taken on whether referenced-based pricing constitutes fixed indemnity coverage or major medical coverage. He said the HBI understands that reference-based pricing creates new challenges to state insurance regulators in seeking to protect consumers from being confused and led to believe they are purchasing major medical coverage. He said the proposed new drafting note also suggests state insurance regulators pair a review of reference-based pricing plans with the health carrier's marketing materials to ensure that the carrier is not developing, marketing, or selling products as a replacement for major medical coverage.

Mr. Wieske said the HBI comments also include its previous suggestions on provisions to be added to Model #171 concerning short-term, limited-duration (STLD) plans, including a proposed definition of the term.

Bill Schiffbauer (Schiffbauer Law Office) discussed his suggested revisions to Section 8B. He said the first revision would amend the definition of "hospital indemnity or other fixed indemnity" insurance based on the definition of that term in the *Supplementary and Short-Term Health Insurance Minimum Standards Model Act (#170)*, the companion model act to Model #171. He said this revised definition adds further interpretation based on the federal excepted benefits statutory conditions that have remained unchanged in federal Public Health Service Act (PHSA) Section 2721(c) and Section 2971(c) since the enactment of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA). He said he also suggests adding language to require a health carrier to annually certify to the state department of insurance (DOI) that its hospital indemnity or other fixed indemnity products are not offered or marketed as major medical coverage or as an alternative or substitute for major medical coverage. He said his last suggested revision is to add a requirement for a prominent disclosure statement in the application above the applicant's signature line. He said this placement provides certainty that the consumer clearly understands that the product being offered for purchase is hospital or other fixed indemnity health insurance coverage and not major medical coverage.

The Subgroup discussed the HBI's and the Schiffbauer Law Office's suggested revisions to Section 8B. Ms. Arp raised a concern about situations when a fixed indemnity plan pays an amount for a certain benefit that substantially or completely covers the actual cost of the service. She said consumers could be confused by this

and led to believe the coverage is major medical coverage. She asked if the Subgroup thinks Section 8B should address this situation. Anna Schwamlein Howard (American Cancer Society, Cancer Action Network—ACS CAN) reiterated the NAIC consumer representatives' concern that the Subgroup rely on disclosures to ensure consumers understand that the fixed indemnity product they are purchasing is not major medical coverage. Ms. Arp acknowledged Ms. Howard's concerns. However, she said some of Ms. Howard's concerns relate to STLD plan coverage, which the Subgroup will address later when it considers what provisions to add to Model #171 for STLD plans. Ms. Bowden said she believes the Subgroup's focus regarding Section 8B is to craft a definition for "hospital indemnity or other fixed indemnity" that aligns with provisions in federal law and regulations on excepted benefits. She said she also believes Section 8B should clarify the issue Ms. Arp raised with respect to the language "regardless of the actual expense incurred" because she does not believe that the situation referenced by Ms. Arp related to this language reflects the intent of the federal law or regulations provisions on excepted benefits. She said, as the Subgroup has discussed, the states have interpreted "regardless of the actual expense incurred" differently when deciding whether a product is a fixed indemnity product or a major medical product. A drafting note to Section 8B could outline both sides of the issue and the different interpretations leaving it up to each state to decide its approach.

After additional discussion, Ms. Arp volunteered to work with other Subgroup members to revise Section 8B to reflect the Subgroup's discussion, including adding a new drafting note to reflect the different approaches taken by the states concerning reference-based pricing plans. She said she would circulate the draft revisions for the Subgroup's consideration and discussion during a future meeting.

Ms. Howard asked Ms. Arp to consider including in the proposed new drafting note language suggesting that in reviewing these products, the states pay particular attention to the benefit amount to be paid under the plan for a specific service to potentially determine if the plan is providing an actual benefit to consumers.

The Subgroup discussed revising the \$40 daily benefit amount in Section 8B because it has not changed since the last time Model #171 was revised in 1998. Mr. Wieske suggested the Subgroup consider replacing the specific dollar amount with a placeholder "X" and including in the proposed new drafting note language suggesting that the states, in reviewing the product filing, consider whether the dollar amount for the benefit included in the filing is so high such that it could lead the consumer to think the product is a major medical product or whether it is so low that the plan does not provide any actual benefit to the consumer. After discussion, Ms. Arp agreed to put language in the proposed new Section 8B drafting note reflecting Ms. Howard's and Mr. Wieske's suggestion.

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

SharePoint/NAIC Support Staff Hub/Member Meetings/2022 NAIC Meetings/Summer National Meeting/Committee Meetings/HEALTH INS and MANAGED CARE (B) COMMITTEE/Reg Framework (B) TF/Accident and Sickness (B) Subgroup/Accident and Sickness Ins Min Stds Subgrp 4-18-22MtgMin.docx



2022 Summer National Meeting
Portland, Oregon

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

Wednesday, August 10, 2022

10:30 – 11:30 a.m.

Meeting Summary Report

The Employee Retirement Income Security Act (ERISA) (B) Working Group met Aug. 10, 2022. During this meeting, the Working Group:

1. Adopted its May 24 minutes, which included the following action:
 - A. Adopted a summary from the case of *Rutledge v. Pharmaceutical Care Management Association* (PCMA) for inclusion in the *Health and Welfare Plans Under the Employee Retirement Income Security Act: Guidelines for State and Federal Regulation* (ERISA Handbook).
2. Heard an update from the U.S. Department of Labor (DOL) regarding its ongoing efforts to implement the federal No Surprises Act (NSA) and mental health parity.
3. Discussed and agreed to update the NAIC Chart on Multiple Employer Welfare Arrangements (MEWA)/Multiple Employer Trust (MET) and Association Plans. NAIC staff will survey the states regarding their laws.
4. Discussed whether to update the ERISA Handbook at this time. The Working Group decided it would be premature to undertake, given all the case law that remains in flux in the courts.
5. Agreed to survey the states regarding their stop loss laws in relation to level funded plans.
6. 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, to continue work on its goals.



2022 Summer National Meeting
Portland, Oregon

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

Thursday, August 11, 2022

1:00 – 1:45 p.m.

Meeting Summary Report

The MHPAEA (B) Working Group met Aug. 11, 2022. During this meeting, the Working Group:

1. Heard a presentation from The Kennedy Forum on insurance coverage for behavioral health emergencies.
2. Heard presentations from the American Psychological Association (APA) and the American Association for Marriage and Family Therapy (AAMFT) on provider experiences with insurance payment for behavioral health treatment and limitations applied by insurers.

2022 Spring National Meeting
Portland, Oregon

PHARMACY BENEFIT MANAGER REGULATORY ISSUES (B) SUBGROUP

Tuesday, August 9, 2022

3:30 – 5:00 p.m.

Meeting Summary Report

The Pharmacy Benefit Manager Regulatory Issues (B) Subgroup of the Regulatory Framework (B) Task Force met Aug. 9, 2022. During this meeting, the Subgroup:

1. Adopted its July 29, June 15, April 25, and Spring National Meeting minutes, which included the following action:
 - A. Heard presentations from various stakeholders on issues from their perspective on the Subgroup's 2022 charge to develop a white paper to: 1) analyze and assess the role pharmacy benefit managers (PBMs), pharmacy services administrative organizations (PSAOs), and other supply chain entities play in the provision of prescription drug benefits; 2) identify, examine, and describe current and emerging state regulatory approaches to PBM business practices, such as price transparency and reporting requirements; rebating; and spread pricing, including the implications of the *Rutledge vs. Pharmaceutical Care Management Association (PCMA)* decision on such business practices; and 3) discuss any challenges, if any, the states have encountered in implementing such laws and/or regulations.
2. Heard a presentation from the PCMA discussing the value of PBMs and the services they provide to plan sponsors. The presentation also discussed how PBMs reduce prescription drug costs for consumers and payers. The presentation described the role PBMs play in the pharmaceutical supply chain, including the effect of PBM negotiated rebates on manufacturer prescription drug prices. The presentation discussed how PBM technology, such as the real-time benefit tool (RTBT), and expertise help patients lead healthier lives.
3. Heard a presentation from the Pharmaceutical Research and Manufacturers of America (PhRMA). The presentation discussed the influence of PBMs on the pharmaceutical supply chain. The presentation discussed how the lack of PBM transparency in its business practices has led to misaligned incentives, which could be contributing to increased costs throughout the health system. The presentation discussed potential policy solutions to address misaligned incentives in the pharmaceutical supply chain, such as anti-steering policies and sharing rebates at the point-of-sale.
4. Heard a presentation from the Oregon Primary Care Association (OPCA). The presentation discussed the federal 340B program, including its history, purpose, and background. The presentation also discussed state 340B anti-discrimination legislative activity prohibiting PBMs from refusing to contract with, reimbursing at a lower amount, imposing different fees, or otherwise discriminating against a 340B covered entity.

Agenda Item #3

**Hear an Update on the Center on Health Insurance Reforms' (CHIR's) Work
—*Maanasa 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
August 10, 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

Research on Public Option Plans

- Update on State Public Option-Style Laws
 - WA
 - CO
 - NV
- In-Depth Analysis of CO's 1332 Waiver for a Public Option-Style Plan
- Upcoming: What the Data Says—Offering Public Option Plans to Workers with Employer-Sponsored Insurance

Enrollment

- California's Marketplace Tries New Tactics to Reduce the Number of Uninsured and Underinsured
- Upcoming: SBM outreach & advertising efforts during the most recent OEP

PHE Unwinding

- Actions State DOIs Can Take to Prepare for the Post-PHE Medicaid Unwinding
- Broker Commissions for Mid-Year Enrollment in the Marketplaces: Options for State Marketplaces and Insurance Regulators to Prevent Discrimination

Abortion and Contraceptive Coverage

- Overview of Federal Action to Improve Access to Mifepristone
- Actions States Can Take to Expand Coverage of Medication Abortions
- Options for Employers Who Want to Cover Out-of-State Travel for Abortion Services

Health Equity

- Continued monitoring and analysis of state action
- Improving Race and Ethnicity Data Collection: A First Step to Furthering Health Equity Through SBMs
- Upcoming: State Efforts to Reduce Diabetes Disparities Through Private Health Insurance Reforms

Implementation of the No Surprises Act

- Interactive map on the roles of federal and state officials on various aspects of the No Surprises Act:
 - Enforcement Strategy - Issuer & Provider Enforcement
 - External Review Process
 - Patient & Provider Dispute Resolution
 - New additions
 - State Ground Ambulance Protections
 - Specified State Laws - Scope and Payment Details
- Upcoming: Issue brief based on interviews with 12 state DOIs on their approaches to NSA implementation and enforcement
- Upcoming: Post on recently enacted state laws related to surprise billing

Other Reading

- Analysis of the Latest Challenge to the ACA Threatening the Availability of Free Preventive Services
- Comparing the Federal and State Network Adequacy Standards Governing Medicaid and Marketplace Plans in Six States
- Upcoming
 - State Efforts to Enforce MHPAEA
 - 50-State Research on Medical Debt Consumer Protections

Questions?

CHIR Publications:

www.chir.georgetown.edu

CHIRblog:

www.chirblog.org

Maanasa Kona, J.D.

Assistant Research Professor

(202) 687-4275

Maanasa.Kona@georgetown.edu

Twitter: @maanasakona

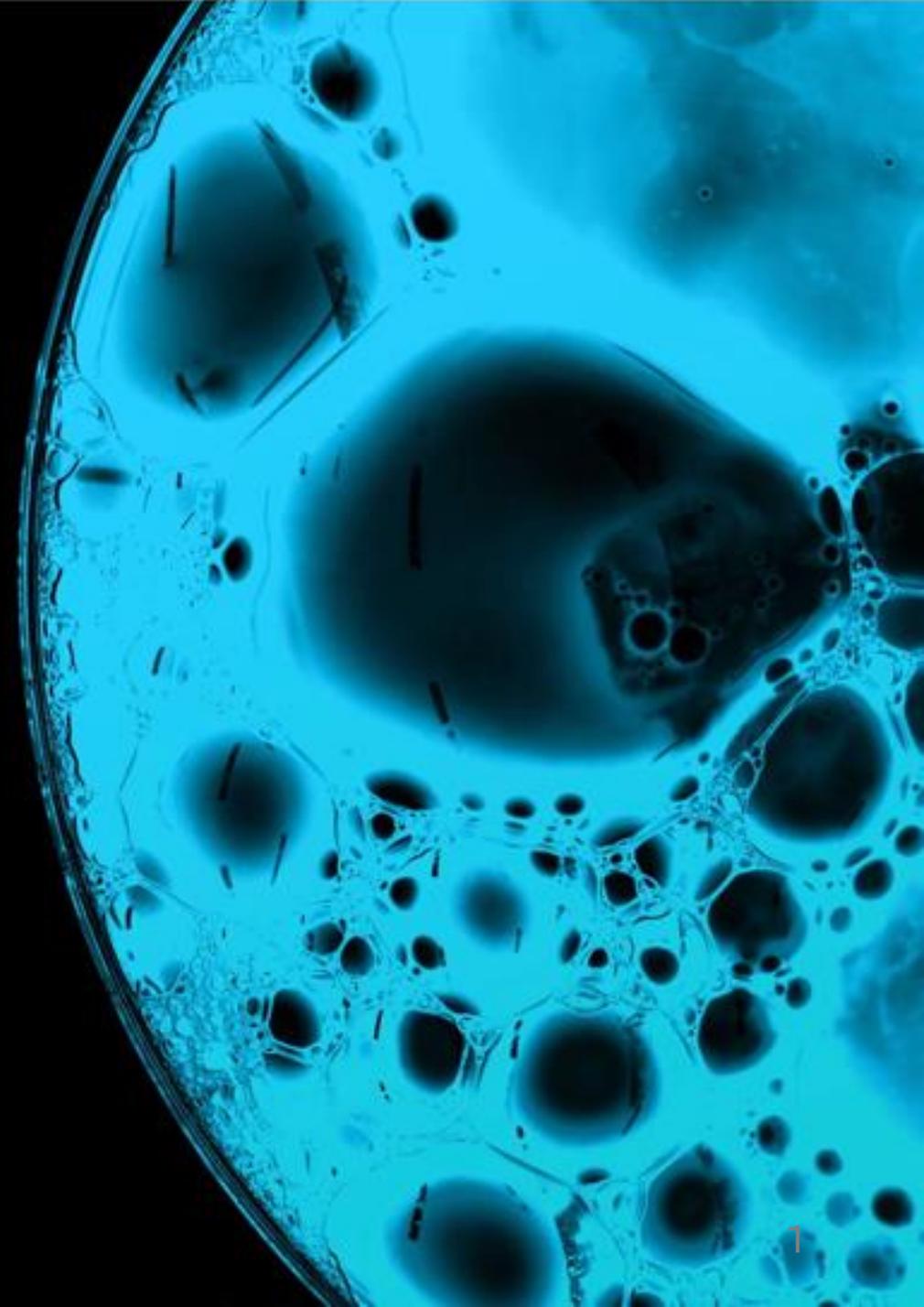
Agenda Item #4

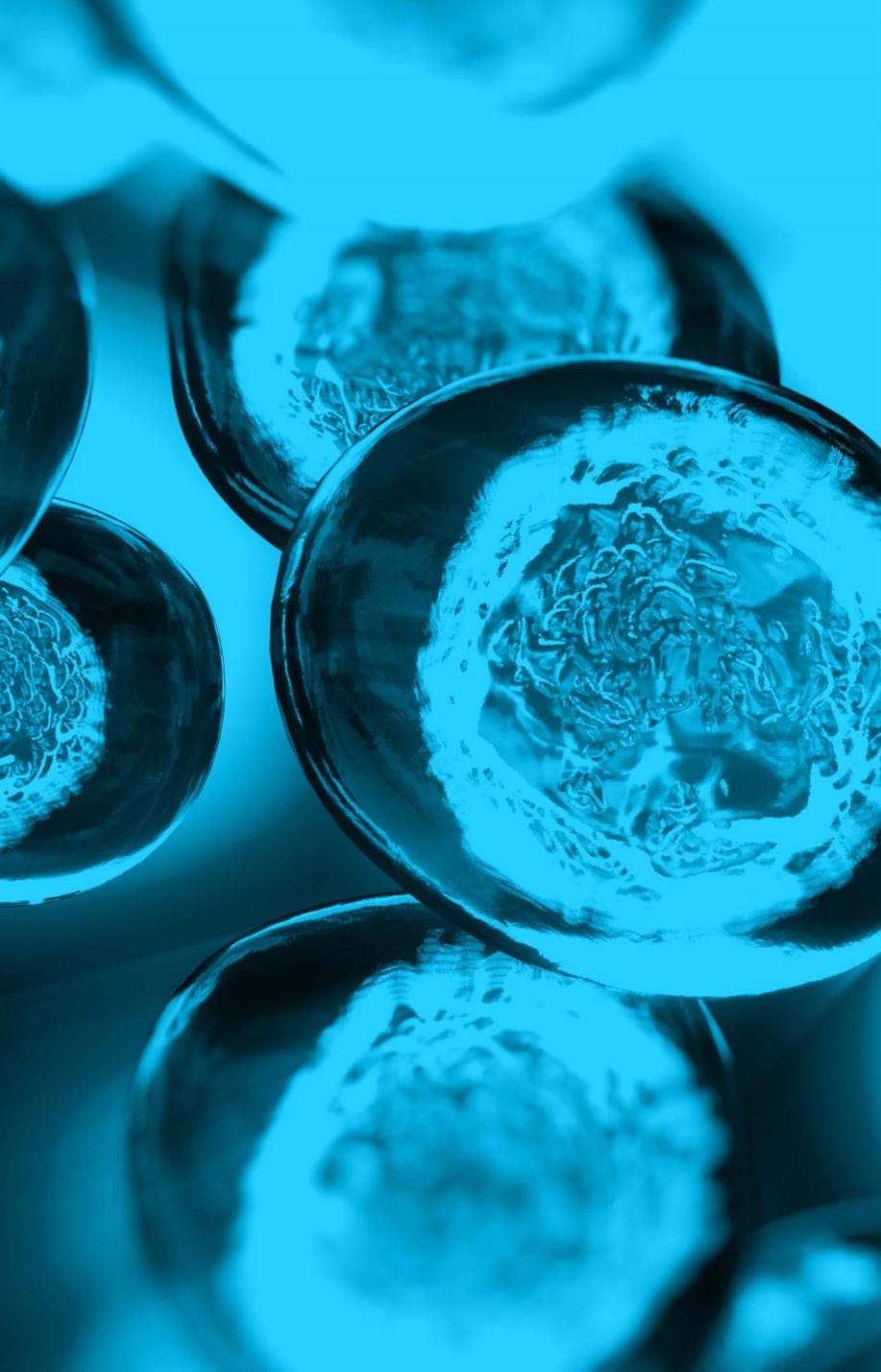
Hear a Discussion on the Usage of the Term “Interchangeable Biosimilar Product” in the *Health Carrier Prescription Drug Benefit Management Model Act (#22)* and its Effect on Prescription Drug Substitutions—*Craig Burton (Association for Accessible Medicines—AAM)*



Increasing Savings through Biosimilars: NAIC Regulatory Framework Taskforce

August 10, 2022



A blue-tinted microscopic image showing several petri dishes containing cell cultures. The cells are visible as dense, fibrous clusters within the dishes, which are arranged in a circular pattern. The lighting is dramatic, highlighting the texture of the cell growth.

Biosimilars Council Mission

- ✓ The Biosimilars Council works to ensure a positive regulatory, reimbursement, political and policy environment for biosimilar products, and educates the public and patients about the safety and effectiveness of biosimilars.
- ✓ Areas of focus include education, access, the regulatory environment, reimbursement and legal affairs.
- ✓ Member organizations include companies or stakeholder organizations working to develop biosimilar products with the intent to compete in the U.S. market.

The Biosimilars Council was created in 2015 to support the growing biosimilars sector and works to increase patient access to lifesaving biosimilar medicines



accord
We make it better

AmerisourceBergen

 **amneal**
BIOSCIENCES

AXINN

 **Biocon**

Dr.Reddy's 

 **FRESENIUS
KABI**

 **LUPIN**
PHARMACEUTICALS, INC.
Research Driven. Quality Committed. Customer Focused.

SANDOZ

teva

Biosimilars = Savings for Patients and States



37
approved

Projected savings through 2025

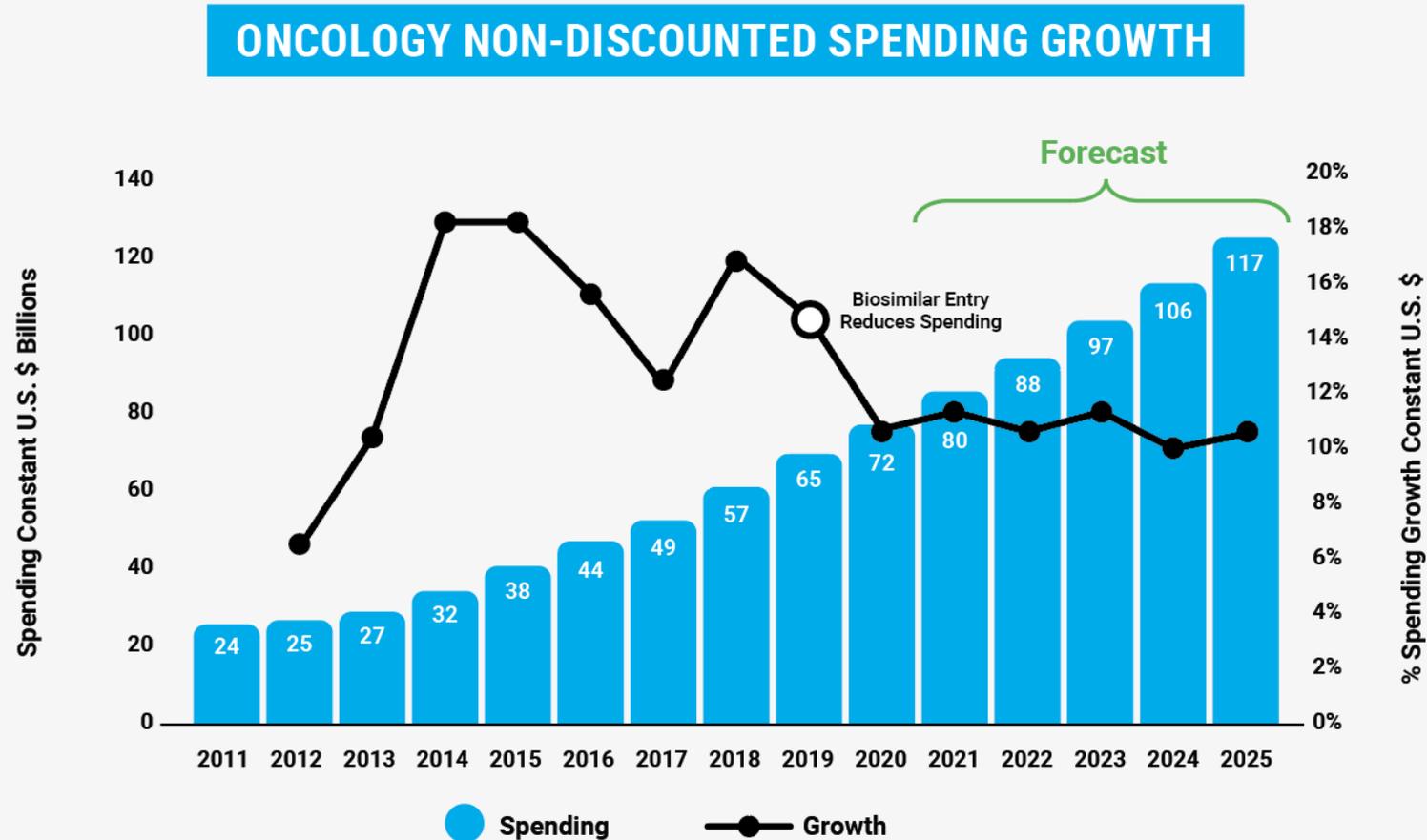
\$133 Billion

22
marketed

Biosimilars have been used in more than **121 million days** of patient therapy and have resulted in almost **10 million incremental days** of therapy.

Biosimilar competition is driving lower prices among biosimilars and their reference products

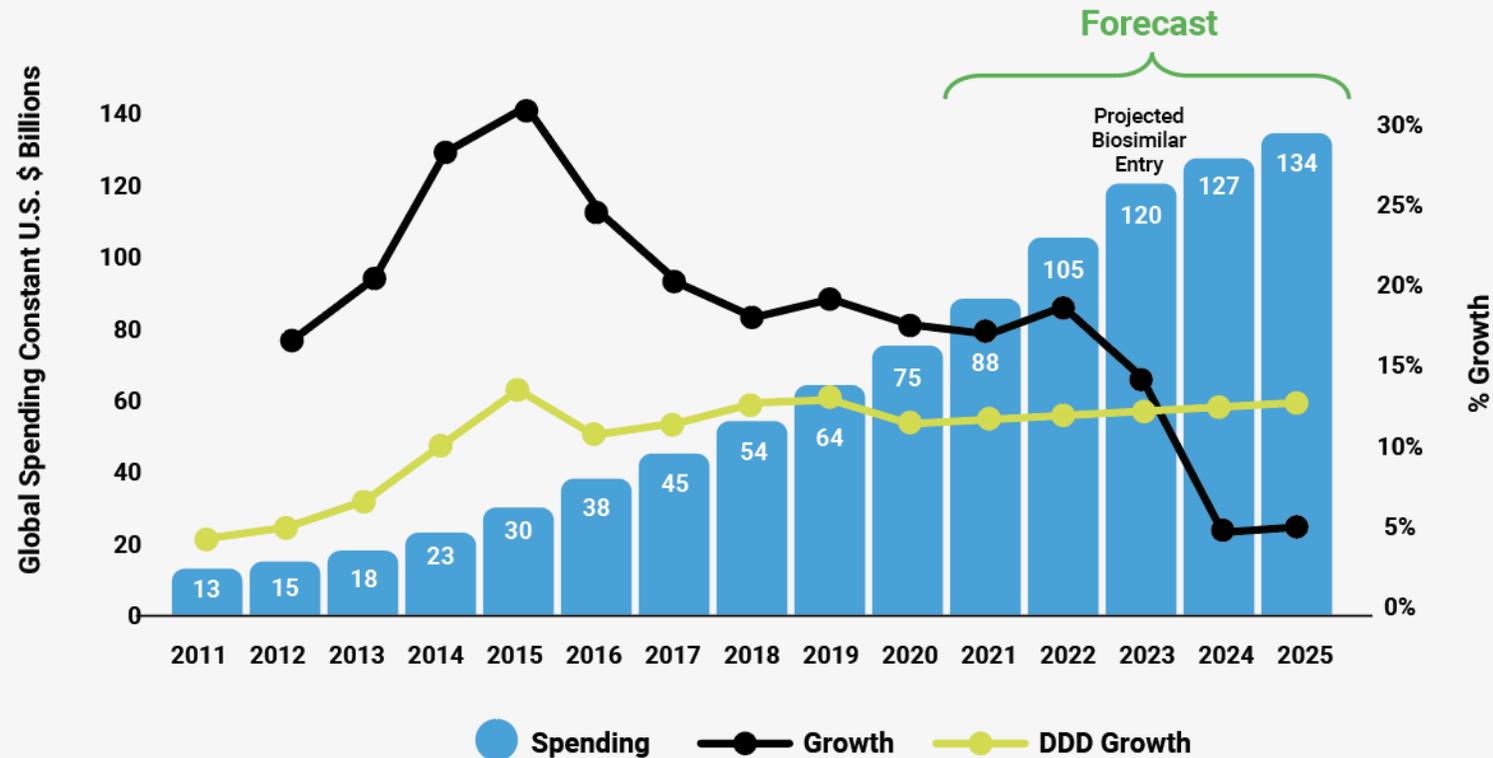
Biosimilars are Reducing Spending



Source: IQVIA Institute for Human Data Science, May 2021. "The Use of Medicines in the U.S.: Spending and Usage Trends and Outlook to 2025."

And Future Savings are Coming

U.S. AUTOIMMUNE NON-DISCOUNTED SPENDING GROWTH



Source: IQVIA Institute for Human Data Science, May 2021. "The Use of Medicines in the U.S.: Spending and Usage Trends and Outlook to 2025."

Updating NAIC's Model Act to Ensure Patient Savings



- Suggested change to the NAIC Health Carrier Prescription Drug Benefit Management Act Model:
 - “Drug substitution” means:

“(2) For biologics, the substitution of a **biosimilar product, as defined in 42 USC §262(i), that the FDA has determined to be biosimilar in accordance with the standards set forth in 42 USC §262(k) or** an interchangeable biosimilar product, which is a biosimilar product, as that term is defined in 42 USC §262(i), the FDA has determined to be interchangeable in accordance with the standards set forth in 42 USC §262(k)(4), and listed as such in the latest edition of or supplement to the FDA Lists of Licensed Biological Products with Reference to Product Exclusivity and Biosimilarity or Interchangeability Evaluations, also known as the Purple Book.

Prioritizing Biosimilars through Formulary Design



Biosimilar vs Interchangeable is not relevant for formulary regulations. The distinction is only meaningful at the pharmacy counter and is not an indication of superior quality.

Biosimilars

FDA-Approval

- Highly similar to the reference product and does not have clinically meaningful differences

Administration

- Prescribed and administered by a physician or other health care provider

Interchangeable Biosimilars

FDA-Approval

- Biosimilar
- Per FDA's requirements, may have undergone additional studies about the effects of switching between biosimilar and reference

Administration

- Typically dispensed by a pharmacist
- Subject to state law, a pharmacist may substitute an interchangeable biosimilar instead of the reference without the prescribing physician's approval

Conclusion – Encouraging Savings through Biosimilars



- Updating NAIC's model would allow formularies to substitute a biosimilar for a reference product:
 - Empowers plans to encourage use of an equally effective, lower cost biosimilar
 - Supports patient access and savings through lower cost biosimilars
 - Does not amend state dispensing requirements for interchangeable products

Agenda Item #5

Hear an Update on the Implementation of the Federal Network Adequacy Standards for Qualified Health Plans (QHPs) in the Federally Facilitated Health Insurance Exchanges—*Brian R. Webb (NAIC)*

Agenda Item #6

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