

REGULATORY FRAMEWORK (B) TASK FORCE

Regulatory Framework (B) Task Force March 23, 2022, Minutes

Accident and Sickness Insurance Minimum Standards (B) Subgroup March 21, 2022, Minutes (Attachment One)

Accident and Sickness Insurance Minimum Standards (B) Subgroup March 7, 2022, Minutes (Attachment Two)

Accident and Sickness Insurance Minimum Standards (B) Subgroup Feb. 14, 2022, Minutes (Attachment Three)

Accident and Sickness Insurance Minimum Standards (B) Subgroup Dec. 6, 2021, Minutes (Attachment Four)

Employee Retirement Income Security Act (ERISA) (B) Working Group March 22, 2022, Minutes (Attachment Five)

Rutledge v. PCMA Case Summary (Attachment Five-A)

Pharmacy Benefit Manager Regulatory Issues (B) Subgroup March 16, 2022, Minutes (Attachment Six)

Pharmacy Benefit Manager Regulatory Issues (B) Subgroup Dec. 11, 2021, Minutes (Attachment Six-A)

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.

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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

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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.

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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

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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.

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Accident and Sickness Insurance Minimum Standards (B) Subgroup
Virtual Meeting
March 21, 2022

The Accident and Sickness Insurance Minimum Standards (B) Subgroup of the Regulatory Framework (B) Task Force met March 21, 2022. The following Subgroup members participated: Laura Arp, Co-Chair (NE); Andy Schallhorn, Co-Chair (OK); Debra Judy (CO); Chris Struk (FL); Robert Wake (ME); Cynthia Amann (MO); Glynda Daniels (SC); Rachel Bowden (TX); Shelley Wiseman and Heidi Clausen (UT); Anna Van Fleet, Mary Block, and Christine Menard-O'Neil (VT); and Ned Gaines (WA).

1. Discussed Revisions to Model #171

The Subgroup continued its discussion of revisions to the *Model Regulation to Implement the Accident and Sickness Insurance Minimum Standards Model Act* (#171). The Subgroup focused its discussion on indemnity products and how best to address regulating such products in the Model #171 revisions given the different product designs, variation in state insurance regulation of the product and federal law and regulations related to the product, and the concept of “excepted benefits.”

Ms. Arp asked for comments on whether a product should be considered an indemnity product when there is a reference price list for procedures the plan would pay for provided outside and not as a part of the contract or policy. Ms. Daniels said South Carolina has a company selling a product designed like this and that South Carolina considers that product to be an indemnity product. She said South Carolina has issued a bulletin that specifies what types of products sold in South Carolina will be considered indemnity products. Ms. Daniels described the provisions in the bulletin. She explained that the key language in the bulletin that South Carolina relies on in determining whether a product is an indemnity product is in Section II, item 2—“The benefits are paid in a fixed dollar amount per period of hospitalization or illness and/or per service (for example, \$100/day or \$50/visit) regardless of the amount of expenses incurred and without regard to the amount of benefits provided with respect to the event or service under any other health coverage.” She said for the product Ms. Arp is referring to, using the language in this bulletin and because it proposes to pay a fixed amount and would pay that amount directly to the consumer, South Carolina determined that it is a fixed indemnity product. Ms. Arp asked what is meant by the language “regardless of the amount of the expenses incurred.” She said when a plan has a price list, which may be calculated using a percentage of what Medicare would pay for a procedure, it uses that as a basis to pay for a procedure, and that is the cost of the expense the consumer incurred. Ms. Daniels said that South Carolina decided that even if the price is determined by a percentage of Medicare, that is still a fixed amount and given that, it determined that it is a fixed indemnity plan.

Ms. Bowden said she understands the different interpretations of what is considered a fixed indemnity product. She said Texas does not have the language “regardless of the amount of the expenses incurred” in its fixed indemnity plan definition regulations. She said Texas approved the sale of the plan in Texas as an “other fixed indemnity” product because it did not seem to “fit” any other category. She said she hopes that the revisions to Model #171 will help states like Texas clarify what is and is not a type of fixed indemnity product. The Model #171 revisions need to provide language that substantively distinguishes the excepted benefit plans from major medical coverage. Ms. Bowden said she personally believes it is problematic to allow what she would consider a type of fixed indemnity product using a reference-based pricing list, which could be seen as essentially offering major medical coverage without being subject to any of the same standards and consumer protections as federal Affordable Care Act (ACA)-compliant major medical coverage.

Ms. Bowden said she would like the Model #171 revisions to address this in some manner and provide more guidance around the “regardless of the amount of the expenses occurred” language.

The Subgroup discussed whether it would be beneficial to add language to Model #171 clarifying this issue. J.P. Wieske (Health Benefits Institute—HBI) said that if the Subgroup wants to add clarifying language, it can probably be done. He cautioned, however, that not all states have taken the same approach to fixed indemnity coverage, including in determining what is and is not fixed indemnity coverage. Given this, the Subgroup might have to add a drafting note explaining this and alerting states that they may want to use other language that is consistent with their regulations for this type of coverage.

The Subgroup also discussed the need for the model revisions to require disclosures and marketing for these products to include clear information on their purpose, how they are intended to be used, the benefits they offer, and what they do and not do with respect to coverage.

Chris Petersen (Arbor Strategies LLC) pointed out that this is a minimum standards model and highlighted the differences in how states regulate them. He suggested that the Subgroup consider language highlighting this in a drafting note. He also urged the Subgroup not to align language in the model with federal regulations because they could change and have changed from presidential administration to presidential administration. Ms. Arp said that she believes there is a need for the Subgroup to clarify these issues with indemnity products because based on discussions she has participated in, the states are looking for clarity.

Lucy Culp (Leukemia & Lymphoma Society—LLS) expressed support for the Subgroup revising the disclosures for fixed indemnity products for more clarity in the language about what benefits they offer and add requirements on where the disclosure language should be placed in the policy, such as the first page or cover page. Ms. Arp agreed that it is important that the Subgroup revise Model #171 to require meaningful disclosures, which ultimately make it easier for state insurance regulators to determine compliance. Ms. Bowden said she does not believe this discussion about indemnity products is a minimum standards issue. She believes it is a definitional and possibly scope issue. “What does fixed indemnity mean?” “What is the scope of this model?” There are many valid interpretations of what this term means and the model’s scope.

Ms. Arp said that based on the discussion during this meeting, there appears to be some desire to provide clarity around fixed indemnity coverage. She asked Subgroup members, interested state insurance regulators, and interested parties to submit language for the Subgroup’s consideration during its April 18 meeting defining “fixed indemnity.” Specifically, she asked for redline language for provision “B. Hospital Indemnity or Other Fixed Indemnity Coverage” and its drafting note on pages 12–13 of the Model #171 working draft that would provide clarity on fixed indemnity coverage—what it is and what it is not.

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

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Accident and Sickness Insurance Minimum Standards (B) Subgroup
Virtual Meeting
March 7, 2022

The Accident and Sickness Insurance Minimum Standards (B) Subgroup of the Regulatory Framework (B) Task Force met March 7, 2022. The following Subgroup members participated: Laura Arp, Co-Chair (NE); Andy Schallhorn, Co-Chair, represented by Cuc Nguyen, Landon Hubbart, and Rebecca Ross (OK); Debra Judy (CO); Howard Liebers (DC); Chris Struk (FL); Robert Wake (ME); Camille Anderson-Weddle (MO); Shari Miles (SC); Rachel Bowden (TX); Shelley Wiseman and Heidi Clausen (UT); and Ned Gaines (WA).

1. Discussed Revisions to Model #171

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

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

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

Subgroup also discussed the different treatment of individual products and group products in the federal rules and Model #171.

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

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

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

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

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

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Draft: 3/8/22

Accident and Sickness Insurance Minimum Standards (B) Subgroup
Virtual Meeting
February 14, 2022

The Accident and Sickness Insurance Minimum Standards (B) Subgroup of the Regulatory Framework (B) Task Force met Feb. 14, 2022. The following Subgroup members participated: Laura Arp, Co-Chair (NE); Andy Schallhorn, Co-Chair (OK); Chris Struk (FL); Robert Wake (ME); Camille Anderson-Weddle, Amy Hoyt, and Cynthia Amann (MO); Rachel Bowden (TX); Heidi Clausen (UT); Anna Van Fleet, Mary Block, Christine Menard-O'Neil, and Jamie Gile (VT); and Ned Gaines (WA).

1. Continued Discussion of Revisions to Model #171

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

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

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

Ms. Arp reiterated her suggestion for the Subgroup to begin with the approach of focusing on supplemental products while keeping in mind the similarities or differences and application for other products, such as STLD plans. The Subgroup continued the discussion of possible approaches, including discussing whether the Subgroup needed to work on the STLD plan provisions first because there is already a regulatory framework for supplemental products. Some stakeholders agreed and suggested that as part of this work, the Subgroup look at whether a particular provision: 1) only applies to STLD plans; 2) only applies to supplemental products; or 3) applies to both types of products.

After additional discussion and to assist the Subgroup on deciding its approach in moving forward with its review, NAIC staff agreed to develop a working draft of Model #171 reflecting the Subgroup's discussions to date. The Subgroup plans to discuss the working draft and continue its discussions on the approach to take for its discussions of revisions to Model #171 during its next meeting March 7.

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

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/Accident and Sickness (B) Subgroup/Accident and Sickness Ins Min Stds Subgroup 2-14-22 MtgMin.docx

Draft: 2/1/22

Accident and Sickness Insurance Minimum Standards (B) Subgroup
Virtual Meeting
December 6, 2021

The Accident and Sickness Insurance Minimum Standards (B) Subgroup of the Regulatory Framework (B) Task Force met Dec. 6, 2021. The following Subgroup members participated: Andy Schallhorn, Co-Chair (OK); Chris Struk (FL); Robert Wake (ME); Sherri Mortensen-Brown (MN); Camille Anderson-Weddle, Amy Hoyt, and Carrie Couch (MO); Gayle Woods (OR); Shari Miles (SC); Rachel Bowden (TX); Shelley Wiseman and Heidi Clausen (UT); Anna Van Fleet, Emily Brown, Mary Block, Christine Menard-O’Neil, and Jamie Gile (VT); Ned Gaines (WA); and Nathan Houdek and Jennifer Stegall (WI).

1. Continued Discussion of Revisions to Model #171

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

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

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

Mr. Wake said he believes there should be one definition of “preexisting condition” but different look-back periods for these two types of coverages. The Subgroup discussed his comments, including the implications of changing the definition on existing policies and contracts. Lucy Culp (Leukemia & Lymphoma Society—LLS) asked about the typical length of a look-back period, such as six months or 12 months. Mr. Wieske said for some types of products, it would probably be about a two-year look-back period. He explained that these types of products typically have limited medical underwriting. As such, the purpose of the look-back period is to protect against an individual purchasing, for example, a cancer-only policy when they knew they had cancer prior to the policy purchase.

The Subgroup discussed potential differences in the typical look-back period for supplementary products and STLD plans. Some interested parties favored a two-year look-back period for both types of coverages as a minimum standard. Other interested parties expressed support, generally, for shorter look-back periods for all coverage types. Ms. Culp said the NAIC consumer representatives suggest a six-month look-back period. Chris Petersen (Arbor Strategies LLC) said based on the provisions in the *Supplementary and Short-Term Health Insurance Minimum Standards Model Act (#170)* (formerly known as the *Accident and Sickness Insurance Minimum Standards Model Act*), the companion model for Model #171, revising the definition of “preexisting condition” to provide for a six-month look-back period would not be possible. He said AHIP could support a two-year look-back period for supplementary products. For STLD plans, he said AHIP would be open to discussing a shorter look-back period because it is a different type of coverage; although, AHIP does not believe a shorter look-back period is needed. Cindy Goff (American Council of Life Insurers—ACLI) said the ACLI supports a two-year look-back period for supplementary products, but the ACLI has no position on STLD plans because none of its members sell such coverage.

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

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

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Draft Pending Adoption

Attachment Five
Regulatory Framework (B) Task Force
3/23/22

Draft: 3/28/22

Employee Retirement Income Security Act (ERISA) (B) Working Group
Virtual Meeting (*in lieu of meeting at the 2022 Spring National Meeting*)
March 22, 2022

The ERISA (B) Working Group of the Regulatory Framework (B) Task Force met March 22, 2022. The following Working Group members participated: Robert Wake, Chair (ME); Yada Horace (AL); Jason Lapham (CO); Andria Seip (IA); Julie Holmes (MO); Paul Hanson (MN); Carrie Couch (MO); Laura Arp (NE); Jeremy Christensen (NV); Tracy Biehn (NC); David Barney (OH); Candy Holbrook (SD); Tanji J. Northrup (UT); Charles Malone (WA); and Richard Wicka (WI). Also participating were: Paige Duhamel (NM) and Jon Thayer (NY).

1. Exposed a Revised Draft Case Summary of the *Rutledge v. Pharmaceutical Care Management Association (PCMA)* Decision for Inclusion in the ERISA Handbook

Mr. Wake said the first item on the agenda is to discuss exposing for comment the revised case summary in the case of *Rutledge v. Pharmaceutical Care Management Association (PCMA)*. He explained that this summary has been exposed in other contexts, but he said the Working Group needs a meaningful comment period to give the opportunity to suggest edits before it officially adopts it for inclusion in the *Health and Welfare Plans Under the Employee Retirement Income Security Act: Guidelines for State and Federal Regulation (ERISA Handbook)*. Ms. Arp said that, in her opinion, the case summary is ready for public comment. There were no objections made.

The Working Group agreed to expose the revised draft case summary (Attachment Five-A) for a 30-day public comment period ending April 21, 2022.

2. Discussed Additional Updates to the ERISA Handbook

Mr. Wake explained that the ERISA Handbook was revised to reflect the 2018 U.S. Department of Labor (DOL) association health plan rule. However, in March 2019, significant provisions of the rule were invalidated in federal court and remanded back to DOL. The current administration is not interested in revisiting the AHP rule, and it remains to be seen whether future administrations might seek to revisit it. The question is whether the Handbook should be revised to reflect this reversal and what it should say instead.

J.P. Wieske (Horizon Government Affairs) cautioned against complete removal of the revisions and suggested that some pieces of it should be archived. He said that although the rule is obsolete, it is still the subject of some public policy debate, and there is likely value to having some of the pieces in the ERISA Handbook available for reference.

Carl Schmid (HIV+Hepatitis Policy Institute) said he is looking forward to commenting on the *Rutledge* summary. He said that it is important to review the entire ERISA Handbook and not just insert this case summary. He said there may be other sections where clarifying changes are needed, and the NAIC funded consumer representatives may have some additional changes to propose in other sections.

Ms. Duhamel said she is interested in updates regarding ERISA preemption of state requests for information post-*Gobeille v. Liberty Mutual Ins. Co.* She said she is aware of at least one case that allowed for a state to obtain information from an ERISA plan that is de minimus. Mr. Wake said this was definitely a topic of interest for the Working Group, even if it is not quite ripe for inclusion in the Handbook.

Draft Pending Adoption

Attachment Five
Regulatory Framework (B) Task Force
3/23/22

Mr. Wake asked whether there was any interest in adding to the ERISA Handbook information about regulatory oversight of fully insured as well as self-funded multiple employer welfare arrangements (MEWAs). Ms. Seip said that Iowa has a regulation on this topic that she is happy to share with the Working Group if they choose to look at adding something to the ERISA Handbook.

Mr. Thayer said New York is seeing a recent proliferation of professional employer organizations (PEOs) treated like large groups under state law but covering mostly small employers. Mr. Thayer said this is a significant issue in New York and that the number of people who have their health care through PEOs is almost as large as the small group market. He said his main concern is the applicability of the look-through rules of the federal Affordable Care Act (ACA) to PEO coverage.

Mr. Wake referenced the 2010 case of *Payroll Solutions Group Ltd. v. Nevada*, where a federal trial court held that a state law cannot decide what is an ERISA plan for purposes of federal law, but states can decide treatment under state law. Mr. Wake acknowledged that analysis is complicated when both what the state law permits and the ACA permits have to be considered, and sometimes states prohibit what the ACA permits, but they cannot permit what the ACA prohibits. Ms. Duhamel said that New Mexico is also seeing increased discussions about PEOs and asked whether other states are as well. Mr. Wake said he is not aware of discussions in Maine.

Having no further business, the ERISA (B) Working Group adjourned into regulator-to-regulator session, pursuant to paragraph 1 (potential or pending litigation or administrative proceedings), paragraph 2 (pending investigations), paragraph 3 (specific companies, entities or individuals), paragraph 8 (consideration of strategic planning issues) and paragraph 9 (any other subject required to be kept confidential) of the NAIC Policy Statement on Open Meetings.

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RUTLEDGE v. PHARMACEUTICAL CARE MANAGEMENT ASS'N,
141 S.Ct. 474 (2020)

In *Rutledge v. PCMA*, the Court upheld an Arkansas law, Act 900, which required pharmacy benefits managers (“PBMs”)¹ to reimburse pharmacies at a price equal to or higher than what the pharmacy paid to buy the drug. Act 900 required PBMs to provide administrative appeal procedures for pharmacies to challenge reimbursement prices that are below the pharmacies’ acquisition costs, and it also authorized pharmacies to decline to dispense drugs when a PBM would provide a below-cost reimbursement. Act 900 applied to all transactions between PBMs and pharmacies, including transactions where the PBM was acting on behalf of a self-insured ERISA plan. Thus, the saving clause was not at issue in this case.

In a suit brought by Pharmaceutical Care Management Association (“PCMA”), a national trade association representing 11 PBMs, the Eastern District of Arkansas had ruled that Act 900 was preempted by ERISA, and the Eighth Circuit affirmed.² Both courts relied on a recent Eighth Circuit decision striking down a similar Iowa law because it “made ‘implicit reference’ to ERISA by regulating PBMs that administer benefits for ERISA plans”³ and “was impermissibly ‘connected with’ an ERISA plan because, by requiring an appeal process for pharmacies to challenge PBM reimbursement rates and restricting the sources from which PBMs could determine pricing, the law limited the plan administrator’s ability to control the calculation of drug benefits.”⁴

The Supreme Court, however, held that because Act 900 “regulates PBMs whether or not the plans they service fall within ERISA’s coverage,” it is analogous to the law upheld by the Court in *Travelers*, “which did not refer to ERISA plans because it imposed surcharges ‘regardless of whether the commercial coverage [was] ultimately secured by an ERISA plan, private purchase, or otherwise.’”⁵ The Court held that under *Travelers*, “State rate regulations that merely increase costs or alter incentives for ERISA plans without forcing plans to adopt any particular scheme of substantive coverage are not preempted by ERISA.”⁶

The Court rejected PCMA’s contention “that Act 900 has an impermissible connection with an ERISA plan because its enforcement mechanisms both directly affect central matters of plan administration and interfere with nationally uniform plan administration.”⁷ The Court acknowledged that Act 900 required ERISA plan administrators to “comply with a particular process” and standards,⁸ but explained that those enforcement mechanisms “do not require plan administrators to structure their benefit plans in any particular manner, nor do they lead to anything more than potential operational inefficiencies” for PBMs.⁹ The Court emphasized that State law

¹ As the term is spelled in Act 900. Supreme Court style refers to “pharmacy benefit managers.”

² *PCMA v. Rutledge*, 891 F.3d 1109 (8th Cir. 2018).

³ 141 S.Ct. at 479, quoting *PCMA v. Gerhart*, 852 F.3d 722, 729 (8th Cir. 2017).

⁴ *Id.* at 479, quoting *Gerhart*, 852 F.3d at 726, 731.

⁵ *Id.* at 481, quoting *Travelers*, 514 U.S. at 656.

⁶ *Id.* at 480, citing *Travelers*, 514 U.S. at 668.

⁷ *Id.* at 481–482.

⁸ *Id.* at 482, quoting PCMA brief at 24.

⁹ *Id.*

governs disputes between plans and providers.¹⁰ The Court held further that ERISA did not preempt Act 900's decline-to-dispense provision, even though it "effectively denies plan beneficiaries their benefits" because any denial of benefits would be the consequence of the lawful state regulation of reimbursement rates and the PBM's refusal to comply.¹¹

Finally, the Court rejected PCMA's claim that the law had an impermissible "reference to" ERISA. As the Court explained, Act 900 "applies to PBMs whether or not they manage an ERISA plan," and Act 900 did not treat ERISA plans differently than non-ERISA plans.¹²

However, *Rutledge* does not represent an open-ended approval of state pharmacy benefit regulation in general. The Court only considered the provisions of the Arkansas PBM law as they stood at the time PCMA filed its preemption challenge. While *Rutledge* was making its way through the appellate courts, Arkansas amended its PBM law to add new requirements and prohibitions, so it is important that *Rutledge* not be read as a finding that the Court analyzed Arkansas' PBM law as it existed in 2020. Additionally, the Court did not address issues that have been raised by other State PBM-pharmacy laws, including laws regulating networks, prohibitions and limitations on corporate practice of medicine, and laws regulating what pharmacies may discuss with their patients. The *Rutledge* decision has opened the door to additional ERISA challenges, which, at the time of this writing are making their way through the courts.

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¹⁰ *Id.*

¹¹ *Id.*

¹² *Id.* at 481.

Draft: 3/18/22

Pharmacy Benefit Manager Regulatory Issues (B) Subgroup
Virtual Meeting
March 16, 2022

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

1. Adopted its 2021 Fall National Meeting Minutes

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

2. Heard an Update from Montana on its PBM Law

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

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

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

regulations related to the licensing requirements, including network adequacy requirements. He said he anticipates Montana will end up licensing about 20 PBMs.

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

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

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

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

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

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

4. Heard an Update on State PBM Law Compilation

Jolie H. Matthews (NAIC) said along with the Subgroup's meeting agenda for today, she distributed two charts: 1) a compilation of state PBM licensing and registration laws; and 2) a compilation of state PBM business practice laws. She said these state PBM law compilations relate to and are meant to support the Subgroup's efforts to complete its 2022 charge to develop a white paper on issues related to the state regulation of certain PBM business practices. She said she received corrections and updates to the charts for inclusion in the next versions

of each chart. She said she hopes to complete the updated versions sometime in late April or early May. She requested additional information from stakeholders on any missing state PBM laws to include in the updated versions.

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

5. Discussed its Spring National Meeting Agenda and Future Meetings

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

6. Discussed State Pharmacy Complaint Processes

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

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

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

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

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Draft: 12/29/21

Pharmacy Benefit Manager Regulatory Issues (B) Subgroup
San Diego, California
December 11, 2021

The Pharmacy Benefit Manager Regulatory Issues (B) Subgroup of the Regulatory Framework (B) Task Force met in San Diego, CA, Dec. 11, 2021. The following Subgroup members participated: TK Keen, Chair (OR); Laura Arp, Vice Chair, and Martin Swanson (NE); Lori K. Wing-Heier (AK); Yada Horace (AL); Alan McClain (AR); Bruce Hinze (CA); Paul Lombardo and Kathy Belfi (CT); Andria Seip (IA); Julie Holmes (KS); Shawn Boggs (KY); Jeffrey Zewe (LA); Kathleen A. Birrane and Mary Kwei (MD); Chad Arnold (MI); Chlora Lindley-Myers and Cynthia Amann (MO); Tracy Biehn (NC); Gale Simon (NJ); Paige Duhamel (NM); Shannen Logue (PA); Brian Hoffmeister (TN); Tanji J. Northrup (UT); Don Beatty (VA); Molly Nollette (WA); Nathan Houdek and Jennifer Stegall (WI); Joylynn Fix (WV); and Denise Burke (WY). Also participating were: David Altmaier (FL); Jon Godfread (ND); and Glen Mulready and Kelli Price (OK).

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

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

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

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

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

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

a. Connecticut

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

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

b. Oklahoma

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

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

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

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

c. Virginia

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

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

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

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

d. Wisconsin

Mr. Houdek discussed the work of the Governor's Task Force on Reducing Prescription Drug Prices before Wisconsin's proposed PBM law was introduced. He said the Task Force held eight public meetings from November 2019 to August 2020. The Task Force heard from 24 organizations representing a multitude of stakeholders. He said the Task Force issued a report in October 2020, which centered on the following key policy provisions: 1) lowering prices and controlling costs; 2) increasing transparency and consumer protections; and 3) access for vulnerable populations. Mr. Houdek said with respect to increasing transparency and consumer protections, among its recommendations, the Task Force recommended the creation of the Office of Prescription Drug Affordability. He said similar to Oklahoma's approach, the Task Force recognized that the Wisconsin DOI does not have the capacity and appropriate expertise to implement and enforce the requirements for a law regulating PBMs and the prescription drug market.

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

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

3. Discussed its Next Steps

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

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