

REGULATORY FRAMEWORK (B) TASK FORCE

Regulatory Framework (B) Task Force Aug. 10, 2022, Minutes

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Regulatory Framework (B) Task Force
Portland, Oregon
August 10, 2022

The Regulatory Framework (B) Task Force met in Portland, OR, Aug. 10, 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); Mark Fowler represented by Yada Horace (AL); Ricardo Lara represented by Tyler McKinney (CA); Michael Conway represented by Kate Harris (CO); Andrew N. Mais represented by Jared Kosky (CT); Karima M. Woods represented by Howard Liebers (DC); Trinidad Navarro represented by Frank Pyle and Tim Li (DE); David Altmaier represented by Chris Struk and Shannon Doheny (FL); Doug Ommen represented by Andria Seip (IA); Dean L. Cameron represented by Weston Trexler and Kathy McGill (ID); Amy L. Beard represented by Alex Peck (IN); Gary D. Anderson represented by Kevin Beagan (MA); Timothy N. Schott represented by Robert Wake (ME); Anita G. Fox represented by Karen Dennis (MI); Chlora Lindley-Myers represented by Carrie Couch and Amy Hoyt (MO); Edward M. Deleon Guerrero represented by Charlette C. Borja (MP); Mike Causey represented by Ted Hamby and Robert Croom (NC); Jon Godfread represented by Chrystal Bartuska (ND); Eric Dunning represented by Laura Arp (NE); Chris Nicolopoulos (NH); Russell Toal represented by Paige Duhamel (NM); Judith L. French represented by Laura Miller (OH); Glen Mulready represented by Andrew Schallhorn (OK); Andrew R. Stolfi represented by TK Keen (OR); Michael Humphreys (PA); Patrick Tigue represented by Alyssa Metivier-Fortin and Courtney Miner (RI); Larry D. Deiter represented by Jill Kruger (SD); Carter Lawrence represented by Brian Hoffmeister (TN); Cassie Brown represented by Rachel Bowden (TX); Jon Pike represented by Tanji J. Northrup (UT); Scott A. White represented by Julie Fairbanks and Julie Blauvelt (VA); Mike Kreidler represented by Molly Nollette and Jane Beyer (WA); Nathan Houdek (WI); and Allan L. McVey represented by Erin K. Hunter (WV). Also, participating was: Erica Weyhenmeyer (IL).

1. Adopted its Spring National Meeting Minutes

Mr. Keen made a motion, seconded by Ms. Kruger, to adopt the Task Force's March 23 minutes (*see NAIC Proceedings – Spring 2022, 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 July 11, June 13, June 6, May 9, and April 18. She said that during these meetings, the Subgroup 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.” Based on the comments received and discussion, she said she developed a chair draft of proposed revisions to Section 8B. The Subgroup 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.

Ms. Arp said the Subgroup also 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.

Ms. Arp said the Subgroup is nearing completion of its work related to Section 8—Supplementary and Short-Term Health Insurance Minimum Standards for Benefits. She said that after it finishes its work on this section, the Subgroup will start reviewing and considering revisions to the disclosure and notice provisions in Model #171. She

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said she believes the Subgroup remains on track 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 Aug. 10. He said that during this meeting, the Working Group adopted its May 24 minutes, which included the adoption of 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). The Working Group 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. He said the Working Group 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. The Working Group also discussed whether to update the ERISA Handbook, but it decided that it would be premature to undertake such a project at this time given all the case law that remains in flux in the courts. He said the Working Group agreed to survey the states regarding their stop loss laws in relation to level funded plans.

Mr. Wake said that following all these discussions, the Working Group adjourned into a 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.

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. She said that in March, the Working Group held a series of regulator-to-regulator sessions to discuss potential changes to the mental health parity chapter of the *Market Regulation Handbook*. The Working Group finished its review and forwarded its suggested revisions to the Market Conduct Examination Guidelines (D) Working Group for its consideration. She said the Market Conduct Examination Guidelines (D) Working Group reviewed the Working Group's suggested revisions and adopted them. The Market Regulation and Consumer Affairs (D) Committee will consider adoption of the revised mental health parity chapter during its Aug. 12 meeting.

Ms. Weyhenmeyer said that in June, the Working Group drafted a letter to the U.S. Congress in support of congressional legislation that would provide grants to the states to assist them with mental health parity plan compliance determination, enforcement, and training. She said that during its meetings, the Working Group has discussed how the states are in different positions regarding their level of expertise in carrying out their mental health parity plan compliance work. She said that regardless of such expertise, most states are working to educate their state on the complexities related to mental health parity plan compliance and would benefit from more educational opportunities for their staff.

Ms. Weyhenmeyer said that during the Working Group's April 5 meeting at the Spring National Meeting, it heard a presentation from Illinois and Washington on a designation in behavioral health parity analysis that the Insurance Regulatory Examiners Society (IRES) has developed. She said the first course related to this designation starts in June. She said that during its April 5 meeting, the Working Group also heard: 1) a presentation from the DOL on mental health parity enforcement activities; and 2) a presentation from the American Psychiatric Association (APA) outlining an example of how insurers may document compliance with mental health parity regulations.

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Ms. Weyhenmeyer said the Working Group plans to meet Aug. 11. During this meeting, the Working Group plans to hear: 1) a presentation from The Kennedy Forum on insurance coverage for behavioral health emergencies; and 2) presentations from the 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. She said that following its open session, the Working Group plans to 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.

Commissioner Clark highlighted the need of state departments of insurance (DOIs) for training in mental health parity plan compliance and applauded the Working Group's efforts related to that issue. She said that this training issue needs to be at the forefront of everyone's minds, particularly each NAIC member. She said she would take steps to ensure it becomes a focus of the NAIC membership.

d. Pharmacy Benefit Manager Regulatory Issues (B) Subgroup

Mr. Keen said the Pharmacy Benefit Manager Regulatory Issues (B) Subgroup met Aug. 9. During this meeting, the Subgroup adopted its July 29, June 15, April 25, and April 4 minutes. He said the Subgroup also heard: 1) a presentation from the PCMA; 2) the Pharmaceutical Research and Manufacturers of America (PhRMA); and 3) the Oregon Primary Care Association (OPCA). He said these presentations focused on issues for the Subgroup to consider as it begins its work to draft the white paper on pharmacy benefit manager (PBM) business practices.

Mr. Keen said he anticipates the Subgroup holding at least one more meeting in late August during which it would hear from at least one additional stakeholder group on the Subgroup's upcoming work on the white paper. He said he anticipates the Subgroup beginning its work on the white paper in September. He said that on Aug. 15, the Subgroup plans meet in 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, to: 1) discuss its approach to the white paper; 2) discuss a draft white paper outline; and 3) seek volunteers from among the Subgroup members to begin drafting sections of the white paper. He said he hopes the Subgroup can complete its work on the white paper by the end of the year.

Commissioner Clark said completing the white paper by the end of the year is an ambitious timeline. She said completing the white paper within that time frame is a laudable goal, but that the Subgroup should not rush its work. Commissioner Schmidt agreed that completing the work by the end of the year should not be set in stone, but it should be a target with the understanding that to ensure robust discussion and stakeholder comment, the white paper may not be finished until sometime in early 2023. Mr. Keen agreed.

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 July 11 (Attachment One), June 13 (Attachment Two), June 6 (Attachment Three), May 9 (Attachment Four), and April 18 (Attachment Five) minutes; the ERISA (B) Working Group, including its Aug. 10 minutes (Attachment Six), which also includes the adoption of the *Rutledge v. Pharmaceutical Care Management Association* (PCMA) case summary for inclusion in the ERISA Handbook; the MHPAEA (B) Working Group, including its April 5 minutes (Attachment Seven); and the Pharmacy Benefit Manager Regulatory Issues (B) Subgroup, including its Aug. 9 minutes (Attachment Eight). The motion passed unanimously.

3. Heard an Update on the CHIR's Work

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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 said the CHIR is researching public option plans and recently published an in-depth analysis of Colorado's federal Affordable Care Act (ACA) Section 1332 waiver for a public option-style plan. The CHIR recently published a brief on the efforts California's state-based insurance marketplace is trying in order to reduce the number of uninsured and underinsured.

Ms. Kona said the CHIR also recently published a brief on actions state insurance regulators can take to prepare for the post-public health emergency (PHE) Medicaid unwinding. She said another issue the CHIR is analyzing is abortion and contraceptive coverage after the recent U.S. Supreme Court ruling in *Dobbs v. Jackson Women's Health Organization*.

Ms. Kona said the CHIR is continuing to monitor and analyze state action related to health equity. She said it recently published a report entitled, "Improving Race and Ethnicity Data Collection: A First Step to Furthering Health Equity Through SBMs."

Ms. Kona said the CHIR is also continuing its work related to the implementation of the NSA as she discussed during her update during the Task Force's March 23 meeting. She said the CHIR plans to release a study on state laws related to surprise billing enacted since the enactment of the NSA. She said the CHIR recently completed a study comparing the federal and state network adequacy standards governing Medicaid and ACA marketplace plans in six states.

Ms. Kona said the CHIR's future work includes: 1) publishing an issue brief on state efforts to enforce the MHPAEA; and 2) a 50-state research project on medical debt consumer protections.

4. Heard a Presentation from the AAM on the Usage of the Term "Interchangeable Biosimilar Product" in Model #22

Craig Burton (Association for Accessible Medicines—AAM) presented on the use of the term "interchangeable biosimilar product" in the *Health Carrier Prescription Drug Benefit Management Model Act* (#22) and its effect on prescription drug substitutions. He first discussed the mission of the Biosimilars Council (Council), which is a division of the AAM. The 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. He said Council member organizations include companies or stakeholder organizations working to develop biosimilar products with the intent to compete in the U.S. market. The Council was created in 2015 to support the growing biosimilars sector and works to increase patient access to biosimilar medicines.

Mr. Burton discussed how biosimilars are currently reducing spending and potential savings in the future. He said the definition of "drug substitution" in Section 3G(2) of Model #22 should be revised as follows to ensure patient savings: "(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(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."

Mr. Burton explained that biosimilar versus interchangeable is not relevant for formulary regulations. The distinction is only meaningful at the pharmacy counter and is not an indication of superior quality. He said that revising Model #22, as the AAM suggests, to allow formularies to substitute a biosimilar for a reference product: 1) empowers plans to encourage the use of an equally effective, lower cost biosimilar; 2) supports patient access and savings through lower cost biosimilars; and 3) does not change state dispensing requirements for interchangeable products.

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Commissioner Clark said that she first became aware of this issue during Kentucky's more recent legislative session during discussions of proposed legislation on step therapy protocols. The Task Force discussed Mr. Burton's presentation, particularly whether there is a need to revise Model #22 as the AAM suggests. After additional discussion, the Task Force decided to have an ad hoc group of Task Force members examine the issues more thoroughly and report back to the Task Force with any recommendations before or at the Fall National Meeting.

5. Heard an Update on the Implementation of the Federal Network Adequacy Standards for QHPs in FFEs

Brian R. Webb (NAIC) provided an update on the implementation of the federal network adequacy standards for qualified health plans (QHPs) in federally facilitated exchanges (FFE). He discussed the history of federal regulators attempting to impose federal network adequacy standards beginning with the Obama Administration, which initially proposed federal network adequacy standards, but after a rocky implementation rollout, the Obama Administration ended its efforts and returned network adequacy oversight to the states.

Mr. Webb said a federal court subsequently ruled this change was arbitrary and capricious and that the federal government must ensure networks are adequate. He said that because of this ruling, federal oversight is scheduled to resume for the 2023 plan year. He said that for QHPs in FFEs, beginning with plan year 2023, the federal Centers for Medicare & Medicaid Services (CMS) will begin implementing time/distance standards for various types of providers and facilities, and beginning in plan year 2024, the CMS will begin implementing wait time standards. To comply with the time and distance standards, at least 90% of QHP enrollees must live within the maximum distance to at least one provider of each type.

Mr. Webb said the proposed regulations include a provision allowing those FFE states that have network adequacy rules that are as stringent as the federal rules and a review process that is as stringent as the federal review process, then the state can determine network adequacy for QHPs in that state. He said that to date, the CMS has found that four states—Michigan, New Hampshire, South Dakota, and West Virginia—satisfy these criteria. For all the FFE states not meeting these criteria, the CMS is in the process of reviewing information from health carriers and determining whether they satisfy the federal network adequacy standards or if the health carrier is “justified” in not meeting the standards. He said there have been ongoing meetings between the CMS and the states to discuss a number of issues as the CMS begins implementation, including issues related to coordination, information-sharing, and enforcement. He said another issue being discussed is whether the states have a role in reviewing or providing information to the CMS on health carrier justifications for not meeting the federal network adequacy requirements.

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
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.

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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 Three-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 Two-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.

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Disability Income Protection Provision Suggested Revisions
Comments on NAIC Consumer Representatives' Initial Suggested Revisions

<p>C. Disability Income Protection Coverage</p> <p>“Disability income protection coverage” is a policy that provides for periodic payments, weekly or monthly, for a specified period during the continuance of disability resulting from either sickness or injury or a combination of them that:</p> <p>(1) Provides that periodic payments that are payable at ages after sixty-two (62) and reduced solely on the basis of age are at least fifty percent (50%) of amounts payable immediately prior to sixty-two (62);</p> <p>(2) Contains an elimination period no greater than: (a) Ninety (90) days in the case of a coverage providing a benefit of one year or less; (b) One hundred and eighty (180) days in the case of coverage providing a benefit of more than one year but not greater than two (2) years; or (c) Three hundred sixty five (365) days in all other cases during the continuance of disability resulting from sickness or injury;</p> <p>(3) Has a maximum period of time for which it is payable during disability of at least six (6) months except in the case of a policy covering disability arising out of pregnancy, childbirth or miscarriage in which case the period for the disability may be one month. (good with change 7/11/22) No reduction in benefits shall be put into effect because of an increase in Social Security or similar benefits during a benefit period;</p> <p>(4) Where a policy provides (good with change 7/11/22) total disability benefits and partial disability benefits, only one elimination period may be required.</p>	
ACLI	<p>Section 8(C)(1) Payments After Age 62 ACLI recommends preserving this provision because some individuals choose to take partial social security benefits at age 62. When this occurs, some carriers will reduce the benefit payments to reflect the income replacement they are receiving from social security when they take leave. This avoids duplicate or inappropriate wage replacement amounts.</p> <p>Section 8(C)(2) Elimination Periods These standards were originally intended to apply only to individual products and having them apply to both group and individual creates some issues as outlined below.</p> <p>ACLI recommends leaving the elimination periods as is. These elimination periods as a minimum standard allow insurers the ability to offer the choice of products with different elimination periods which can translate into lower premiums.</p>

For groups specifically, the elimination period should be flexible to allow the employer to customize a plan that is the most appropriate and that considers the employer's paid sick leave, paid time off, paid family or medical leave, salary continuation plans, and/or whether the employer offers short term disability coverage. This highlights a key difference between individual and group policies: that group policies must take into account all other employee benefits, which will vary widely from employer to employer.

As a **specific illustration** of wording for the model regulation to provide for the flexibility requested above, **we suggest the following:** *"Longer elimination periods are permissible if the insured is in receipt of income replacement benefits prior to the start of disability benefits or if the design of the long-term disability plan is selected by a group policyholder on behalf of the members of the group."*

The proposed changes would create an overly restrictive minimum standard for group policies more so than any state currently requires.

Additionally, longer elimination periods can be used in underwriting as an option for consumers should an underwritable condition or circumstance be discovered during the medical underwriting phase. The longer elimination period allows insurers to offer some level of coverage instead of declining coverage outright. Consumers often choose this option to lower the cost of premium.

Section 8(C)(3) Benefit Duration

ACLI requests clarification on the intent of the change from one month to three months for disabilities arising out of pregnancy, childbirth, or miscarriage because this is typically treated the same as other conditions and as illness. The proposed change would imply that the maximum benefit duration for short term disability plans would become three months. There are some group plans with shorter benefit durations that would need to be increased as a result. ACLI is unsure if this was the intent and, if so, would recommend against the change to keep the lower-cost option available for those employers who have chosen it and any who may choose it in the future.

ACLI recommends clarifying that short term disability plans are exempt from the requirement for disability plans to have a maximum benefit duration of six months. Two of the most popular short term maximum payment durations requested by employers are 13 weeks and 26 weeks, which coordinate with 90-day and 180-day elimination periods respectively. Insurers would appreciate a clarification that these types of plans comply with the minimum standards.

<p>AHIP</p>	<p>Section 8 (C) (1) states that disability income protection coverage:</p> <p><i>(1) Provides that periodic payments that are payable at ages after sixty-two (62) and reduced solely on the basis of age are at least fifty percent (50%) of amounts payable immediately prior to sixty-two (62);</i></p> <p>AHIP supports the current language that references age sixty-two (62), which is the earliest time one may choose to receive Social Security retirement benefits. The NAIC Subgroup is asking for specific comments regarding the age a policy could lower the benefit payment amount. Given that this minimum age may change in the future, AHIP would also support revising the specific age of 62 to a more flexible reference such as <i>“the Social Security retirement age.”</i></p> <p>Section 8 (C) (2) recognizes the need for different elimination periods for different levels of benefits that disability income protection policies offer. We support the current elimination periods outlined in this section.</p> <p>The NAIC Subgroup is asking for specific comments on the “appropriate” elimination period for policies providing benefits at various lengths of coverage. AHIP would like to note that the Texas Department of Insurance has suggested that this provision be simplified and modified “to provide that an elimination period cannot exceed 50% of the benefit period.” AHIP would also support this suggested change.</p> <p>Section 8 (C) (3) requires a minimum benefit duration of three (3) months² payable after a disability and allows a one month minimum for a disability arising out of pregnancy, childbirth or miscarriage.</p> <p>The NAIC Subgroup is asking for specific comments on why there is a separate provision for a disability arising out of pregnancy, childbirth or miscarriage. AHIP believes that all disabilities, including pregnancy, childbirth or miscarriage should be treated equally as other disabilities, as mandated by the Pregnancy Discrimination Act of Title VII of the Civil Rights Act. A separate reference for disability arising out of pregnancy, childbirth or miscarriage, is unnecessary. Our suggested redlined edit follows:</p> <p><i>(3) Has a maximum period of time for which it is payable during disability of at least three (3) months. No reduction in benefits shall be put into effect because of an increase in Social Security or similar benefits during a benefit period.</i></p>
<p>Health Benefits Institute (HBI)</p>	<p>Section 8 (C) (1).</p> <p>We believe the language is intended to reflect the fact that insurers are obligated to provide coverage to reflect that the insurer should pay the maximum benefit (i.e. the number of days, months, or years of coverage) until the consumer’s normal retirement age. Insurers will not actually reduce the amount of periodic payments contracted for, but rather stop making payments at the retirement age. This should reflect current disability policy.</p> <p>We would suggest the following language to clarify the issue:</p>

	<p>(1) Provides that periodic payments that are payable at ages after sixty-two (62) as calculated by the Age Discrimination in Employment Act schedule I or schedule II or until social security normal retirement age (SSNRA) as determined by the policy;</p> <p>Drafting Note: The intent of this section is to ensure that disabled employees who are covered under a disability policy are covered under their maximum time benefit or until their social security normal retirement age (specifically when the disabled employee is able to claim 100% of their social security benefits). Some employer plans may be covered under the Age Discrimination in Employment Act which may require a different benefit schedule.</p> <p>Section 8 (C) (2). The current language includes significant employer flexibility surrounding the elimination period of benefits. We believe preserving this language is vital.</p> <p>We urge the committee not to reduce consumer options in purchasing elimination periods. We agree with the general comments that support the affordability of coverage – ensuring that consumers can continue to afford this coverage. More importantly is the impact on employer benefits. Shortening elimination time frames will lead to employers reducing employee benefits like sick leave and PTO which typically pay 100% of salary for an insured benefit which provides less than 100% of salary.</p> <p>Section 8 (C) (3). It is our understanding that current disability policies cover disability arising from pregnancy the same as any other disability. As a result, we believe this section can be deleted.</p>
<p>NAIC consumer representatives</p>	<p>After hearing the conversation at the Working Group’s meeting on May 9, we would like to offer an amended version of our previous comments (first offered in June of 2019). We strongly believe that with respect to the definition of disability income protection, any reduction in benefits related to a person’s age should be tied an individual’s eligibility for full Social Security retirement benefits – not their eligibility for early retirement benefits.</p> <p>Amended Suggested Revisions:</p> <p>“Disability income protection coverage” is a policy that provides for periodic payments, weekly or monthly, for a specified period during the continuance of disability resulting from either sickness or injury or a combination of them that:</p>

(1) Provides that a plan is prohibited from reducing periodic payments based on age, except that a plan may reduce periodic payments provided that reductions not take place until the individual has reached their full retirement age to receive Social Security benefits, and those payments are at least 50% of amounts payable prior to their reaching that age ~~periodic payments that are payable at ages after sixty-two (62) and reduced solely on the basis of age are at least fifty percent (50%) of amounts payable immediately prior to sixty-two (62);~~

Drafting Note: States should be aware that the term “full retirement age” is the age at which an individual will start receiving full retirement benefit amounts from Social Security. The full retirement age will differ depending on the age of the individual. The full retirement age is 66 for individuals born between 1943 and 1954. The full retirement age increases gradually for individuals born between 1955 and 1960, until it reaches 67. For individuals born after 1960, their full retirement age is 67.

More information is available at

<https://www.ssa.gov/benefits/retirement/learn.html#:~:text=The%20full%20retirement%20age%20is,are%20payable%20at%20age%2067.>

(2) Contains an elimination period no greater than: (a) ~~Ninety (90)~~ Thirty (30) days in the case of a coverage providing a benefit of one year or less; (b) ~~One hundred and eighty (180)~~ Ninety (90) days in the case of coverage providing a benefit of more than one year but not greater than two (2) years; or (c) ~~Three hundred sixty five (365)~~ One hundred and eighty (180) days in all other cases during the continuance of disability resulting from sickness and/or injury;

(3) Has a maximum period of time for which it is payable during disability ~~of at least six (6) months except in the case of a policy covering disability arising out of pregnancy, childbirth or miscarriage in which case the period for the disability may be one month.~~ No reduction in benefits shall be put into effect because of an increase in Social Security or similar benefits during a benefit period;

(4) Where a policy provides both total disability benefits and partial disability benefits, only one elimination period may be required.

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 Three-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.

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Chair Draft Suggested Indemnity Provision Language Revisions
 Comments on Suggested Revisions
 (Assuming the chair suggested revisions are accepted)

B. Hospital Indemnity or Other Fixed Indemnity Coverage

(1) “Hospital indemnity or other fixed indemnity coverage” provides a benefit for hospital confinement or another health-related event based on a fixed dollar amount, regardless of the amount of expenses incurred, without coordination with any other health coverage, and consistent with the requirements for excepted benefits under 42 U.S.C. §300gg-91(c)(3) and its implementing regulations.

(2) “Hospital indemnity coverage” may provide a single lump sum benefit for hospital confinement of not less than \$[X], and/or a daily benefit for hospital confinement on an indemnity basis in an amount not less than \$[X] per day and not less than thirty one (31) days during each period of confinement for each person insured under the policy.

(3) Coverage shall not be excluded due to a preexisting condition for a period greater than twelve (12) months following the effective date of coverage of an insured person unless the preexisting condition is specifically and expressly excluded.

Drafting Notes: Hospital indemnity or other fixed indemnity coverage is recognized as supplemental coverage. Any hospital indemnity or other fixed indemnity coverage, therefore, must be payable regardless of other coverage. The same general rule should apply so that group insurance cannot reduce its benefits because of the existence of hospital indemnity or other fixed indemnity coverage. Section 3H(4) of the *Coordination of Benefits Model Regulation* states that the definition of a plan (for the purposes of coordination of benefits)...shall not include individual or family insurance contracts....” States should consider using this language to prevent benefit reductions that could otherwise occur because of the existence of hospital indemnity or other fixed indemnity coverage purchased by the insured.

For indemnity products that are triggered by a variety of health events and provide a variety of daily benefit dollar amounts, regulators should examine the amount payable per day and the total amount payable per year or lifetime to determine whether an indemnity product’s benefits resemble comprehensive major medical coverage. Indemnity products should not be developed, marketed, or sold as a replacement for major medical coverage.

ACLI

(1) “Hospital indemnity or other fixed indemnity coverage” may include but is not limited to a benefits for hospital confinement or another health-related events based on a fixed dollar amount or fixed percentage, regardless of the amount of expenses incurred, without coordination with any other health coverage, and consistent with the requirements for excepted benefits under 42 U.S.C. §300gg-91(c)(3) and its implementing regulations.

<p>AHIP</p>	<p>(1) “Hospital indemnity or other fixed indemnity coverage” provides a benefit for hospital confinement or another specified event based on a fixed dollar amount, regardless of the amount of expenses incurred, without coordination with any other health coverage, and consistent with the requirements for excepted benefits under 42 U.S.C. §300gg-91(c)(3) and its implementing regulations.</p> <p>(2) “Hospital indemnity coverage” may provide a single lump sum benefit for hospital confinement of not less than \$[X], and/or a daily benefit for hospital confinement on an indemnity basis in an amount not less than \$[X] per day for each person insured under the policy.</p>
<p>Health Benefits Institute (HBI)</p>	<p style="text-align: center;">*****</p> <p>(2) “Hospital indemnity coverage” may provide a single lump sum benefit for hospital confinement of not less than \$[X], and/or a daily benefit for hospital confinement on an indemnity basis in an amount not less than \$[X] per day and not less than [X] days during each period of confinement for each person insured under the policy.</p>
<p>NAIC consumer representatives</p>	<p style="text-align: center;">*****</p> <p>(3) Coverage shall not be excluded due to a preexisting condition for a period greater six (6) months following the effective date of coverage of an insured person unless the preexisting condition is specifically and expressly excluded.</p> <p>Drafting Notes: Hospital indemnity or other fixed indemnity coverage is recognized as supplemental coverage. Any hospital indemnity or other fixed indemnity coverage, therefore, must be payable regardless of other coverage. The same general rule should apply so that group insurance cannot reduce its benefits because of the existence of hospital indemnity or other fixed indemnity coverage. Section 3H(4) of the <i>Coordination of Benefits Model Regulation</i> states that the definition of a plan (for the purposes of coordination of benefits)...shall not include individual or family insurance contracts...” States should consider using this language to prevent benefit reductions that could otherwise occur because of the existence of hospital indemnity or other fixed indemnity coverage purchased by the insured.</p> <p>For indemnity products that are triggered by a variety of health events and provide a variety of daily benefit dollar amounts, regulators should examine the amount payable per day and the total amount payable per year or lifetime to determine whether consumers could reasonably perceive an indemnity product’s benefits resemble comprehensive major medical coverage. Indemnity products should not be developed, marketed, or sold as a replacement for major medical coverage.</p> <p>Drafting Note: In setting the minimum daily or lump sum benefit amounts, states should examine the extent to which the benefit amount is in line with a reasonable expectation of a consumer’s out-of-pocket costs. State regulators should also</p>

	<p>examine these benefit amounts to determine whether they could reasonably be construed as violating the state’s <i>Unfair Trade Practices Act</i> [#880].</p>
<p>William G. Schiffbauer Law Office</p>	<p>B. Hospital Indemnity or Other Fixed Indemnity Coverage</p> <p>(1) In General. “Hospital indemnity or other fixed indemnity coverage” provides benefits for specified events based on a fixed dollar amount, regardless of the amount of expenses incurred, without coordination with any other health coverage.</p> <p>(2) Hospital Indemnity Coverage. “Hospital indemnity coverage” may provide a single lump sum benefit fixed dollar benefit for hospital confinement and/or a fixed dollar daily benefit for hospital confinement in addition to benefits for other specified events on an indemnity basis.</p> <p>(3) Other Fixed Indemnity Coverage. Provides benefits for specified events based on a fixed dollar amount, regardless of the amount of expenses incurred, and without coordination with any other health coverage.</p> <p>(4) Preexisting Conditions. Coverage shall not be excluded due to a preexisting condition for a period greater than twelve (12) months following the effective date of coverage of an insured person unless the preexisting condition is specifically and expressly excluded.</p> <p>Drafting Notes: Hospital indemnity or other fixed indemnity coverage is supplemental coverage. Any hospital indemnity or other fixed indemnity coverage, therefore, must be payable regardless of other coverage. The same general rule should apply so that group insurance cannot reduce its benefits because of the existence of hospital indemnity or other fixed indemnity coverage. Section 3H(4) of the <i>Coordination of Benefits Model Regulation</i> states that the definition of a plan (for the purposes of coordination of benefits)...shall not include individual or family insurance contracts....” States should consider using this language to prevent benefit reductions that could otherwise occur because of the existence of hospital indemnity or other fixed indemnity coverage purchased by the insured.</p> <p>For indemnity products that are triggered by a variety of health events and provide a variety of daily benefit dollar amounts, regulators should examine the amount payable per day and the total amount payable per year or lifetime to determine whether an indemnity product’s benefits resemble comprehensive major medical coverage. Indemnity products should not be developed, marketed, or sold as an alternative to, or substitute for, or replacement for major medical coverage. It is the marketing of supplementary coverage as an alternative, substitute or replacement for major medical coverage that presents the unfair trade practice, and not the supplementary coverage itself when it is offered and marketed as supplementary excepted benefits coverage.</p>

Vermont Division of Insurance	These proposed changes broaden the definition of indemnity to match the excepted benefit rules for individual coverage. Vermont uses this regulation to regulate group supplemental health insurance as well. If any state used it for that purpose perhaps a drafting note should be added to address that these standards are designed for individual insurance and that the group excepted benefit rule should be consulted for states using this regulation for group insurance. 45 CFR 146.145.
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SharePoint/NAIC Support Staff Hub/Member Meetings/B CMTE/RFTF/Accident and Sickness Subgrp/Indemnity Language Suggested Revisions June 2022 clean.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.

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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.

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Draft Pending Adoption

Attachment Six
Regulatory Framework (B) Task Force
8/10/22

Draft: 8/17/22

Employee Retirement Income Security Act (ERISA) (B) Working Group
Portland, Oregon
August 10, 2022

The Employee Retirement Income Security (ERISA) (B) Working Group of the Regulatory Framework (B) Task Force met in Portland, OR, Aug. 10, 2022. The following Working Group members participated: Robert Wake, Chair (ME); Yada Horace (AL); Kate Harris (CO); Howard Liebers (DC); Andria Seip (IA); Julie Holmes (KS); Peter Brickwedde and Julia Dreier (MN); Carrie Couch (MO); Robert Croom (NC); Laura Arp (NE); Stephanie McGee (NV); Rebecca Ross (OK); Jill Kruger (SD); Tanji Northrup (UT); Charles Malone (WA); and Richard Wicka (WI).

1. Adopted its May 24 Minutes

Mr. Wake said the Working Group met May 24 to adopt a summary of the U.S. Supreme Court case *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).

Mr. Wake made a motion, seconded by Ms. Kruger, to adopt the Working Group's May 24 (Attachment Six-A) minutes. The motion passed unanimously.

2. Heard an Update from the DOL

Amber Rivers (U.S. Department of Labor—DOL) gave an update on activity at the DOL. She said the DOL is working on implementation of the federal No Surprises Act (NSA), which was passed as part of the federal Consolidated Appropriations Act, 2021 (CAA). She said that the DOL has been working with the U.S. Department of Health and Human Services (HHS) and the U.S. Department of the Treasury (Treasury) on information sessions. She said there have been a number of lawsuits filed and that the DOL received a couple of adverse decisions vacating some of the core provisions that related to the interim final rules issued last October establishing the independent dispute resolution process. She said that the agencies have been working on additional rulemaking to address those vacated provisions.

Ms. Rivers said the DOL was also working on mental health parity implementation. She said in January, the DOL, HHS, and Treasury issued their Report to Congress addressing compliance with the federal Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA) generally and serving as the disclosure requirement implemented by the CAA. A second Report to Congress is currently underway. Ms. Rivers also said that the DOL, HHS and Treasury are working on a new proposed rule to address the new mental health parity requirements under the CAA.

Beth Baum (DOL) said that on July 23, the DOL, HHS, and Treasury issued a frequently asked questions (FAQ) document clarifying access to contraceptive coverage required under the federal Affordable Care Act (ACA). She also said that the DOL, HHS, and Treasury are working on a proposed rule addressing the moral and religious exemption.

3. Discussed Updating the NAIC Chart on MEWA/MET and Association Plans

Mr. Wake explained that there is an NAIC chart on state laws addressing multiple employer welfare arrangements (MEWAs) and multiple employer trusts (METs) that could use some updating. He said that it might be useful to

Draft Pending Adoption

Attachment Six
Regulatory Framework (B) Task Force
8/10/22

survey the states to see if there are any new laws or regulations. He said that the chart could be turned into a compendium of state options for regulating. Mr. Wake said that he would like to know if any states regulate fully insured MEWAs—not just the insurer providing the coverage, but the reserves and finances of the MEWA itself—which is specifically allowed under ERISA §514(b)(6)(A)(i). Ms. Seip said that Iowa promulgated association health plan (AHP) regulations in response to the 2018 AHP rule issued by the DOL in 2018, which is not enforceable since the District Court for the District of Columbia vacated key provisions of the AHP rule. Ms. Seip said she would like to know how other states have addressed the situation and what have they done with their rules. Mr. Wake said when Maine enacted the AHP section of its small group law, it included a clause requiring compliance with federal requirements. Jennifer Cook (NAIC) said she will send an email survey to the states regarding their laws.

4. Discussed Whether to Update the ERISA Handbook

Mr. Wake explained that during the drafting of the *Rutledge v. Pharmaceutical Care Management Association* (PCMA) summary for inclusion in the ERISA Handbook, the Working Group received some comments pointing out that the Working Group's last comprehensive review of the ERISA Handbook did not catch all the obsolete points. Mr. Wake said he wondered if it was time to undertake another comprehensive review of the ERISA Handbook. Ms. Arp said her recollection was that the comment to revisit the ERISA Handbook was made in the context of an expansive reading of the *Rutledge* decision and, in her opinion, it is premature to revisit the rest of the ERISA Handbook based on the *Rutledge* decision when the implications of that decision on other laws is still unknown. Mr. Wake said he was thinking that the comments were referencing that the Working Group had not fully digested some of the older cases, but he agreed with Ms. Arp's point that there is likely to be litigation in the near future, and the Working Group is better off waiting a little longer to see how the ERISA case law evolves. He said even the 2018 AHP rule is not completely settled. He said DOL has not replaced or repealed the rule, and as a result, he would not be comfortable amending the ERISA Handbook to remove the information. The Working Group decided it would be premature to undertake a revision of the ERISA Handbook at this time.

Having no further business, the ERISA (B) Working Group adjourned.

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Draft: 5/26/22

Employee Retirement Income Security Act (ERISA) (B) Working Group
Virtual Meeting
May 24, 2022

The ERISA (B) Working Group of the Regulatory Framework (B) Task Force met May 24, 2022. The following Working Group members participated: Robert Wake, Chair (ME); Yada Horace (AL); Jason Lapham (CO); Doug Ommen and Andria Seip (IA); Julie Holmes (KS); Victoria Bares and Norman Barrett Wiik (MN); Amy Hoyt (MO); Ted Hamby (NC); Laura Arp (NE); Jeremy Christensen (NV); Laura Miller (OH); Andrew Schallhorn (OK); Tanji J. Northrup (UT); Andrea Jensen (WA); and Richard Wicka (WI).

1. Discussed the May 6 Draft Case Summary of the *Rutledge v. PCMA* Decision for Inclusion in the ERISA Handbook

Mr. Wake said the first item on the agenda is to discuss the May 6 revision of the summary in 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). He explained that the May 6 draft incorporates the comments that were submitted on the Feb. 16 draft by the April 21 deadline. Carl Schmid (HIV+Hepatitis Policy Institute) said the NAIC consumer representatives identified other parts of the ERISA Handbook that need updating. Mr. Wake explained that he would like to focus on incorporating the Rutledge decision into the “Key U.S. Supreme Court Opinions on ERISA’s Preemption Provisions” section of the ERISA Handbook, but he agreed that additional updates to the ERISA Handbook should be considered as part of a more full-scale review at some point in the future.

Cari Lee (Step toe & Johnson LLP) asked for some clarification regarding what was meant by the third sentence in the summary: “Unlike the PBM laws in some states, Act 900 was not structured as an insurance law.” She said it is unclear because Act 900 involves the Arkansas Department of Insurance (DOI). Mr. Wake said the next sentence was intended to clarify what he meant: “It applied to all transactions between PBMs and pharmacies, including transactions where the PBM was acting on behalf of a self-insured ERISA plan, so Arkansas could not rely on the saving clause as its defense against an ERISA preemption challenge.” Mr. Wake suggested making the following revision to the sentence: “Unlike the PBM laws in some states, Act 900 was not strictly structured as an insurance law.” The Working Group agreed that the addition of “strictly” is a helpful change.

Kris Hathaway (America’s Health Insurance Plans—AHIP) suggested the following two revisions to the last paragraph the Rutledge summary:

However, the Court limited its decision to only considered the provisions of the Arkansas PBM law as they stood at the time PCMA filed its preemption challenge, not the amendments the legislature subsequently made while *Rutledge* was making its way through the appellate courts. Additionally, the Court did not address preemption under Medicare Part D and issues that have been raised by PBM and pharmacy laws in other states, including laws regulating provider networks and laws addressing contractual restrictions on discussions between pharmacies and patients. Subsequent to the *Rutledge* decision, additional ERISA challenges continue, at the time of this writing, to make their way through the courts.

Mr. Wake said with respect to the first suggested change, he believes the existing language is more accurate. He said saying the Court “limited its decision” implies certain issues were before the Court and the Court decided not to consider them, which is not the case. The Arkansas law was later amended, but those amendments were never before the Court, so “only considered” language seems to accurately describe the situation. With respect to the second suggested revision, Mr. Wake said Medicare Part D seems to be a peripheral issue, but he agreed that the suggested revision to mention Medicare Part D as an example of an issue not addressed in this case could be helpful for future readers to place the decision in context.

Ms. Arp made a motion, seconded by Mr. Wicka, to adopt the May 6 draft case summary with the “strictly” and “preemption under Medicare Part D and” revisions discussed on the call (Attachment Six-A1). The motion passed unanimously.

Having no further business, the ERISA (B) Working Group adjourned. sites/NAICSupportStaffHub

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Adopted by ERISA (B) Working Group on May 24, 2022 for inclusion in the *Health and Welfare Benefit Plans Under the Employee Retirement Income Security Act: Guidelines for State and Federal Regulation*

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

In *Rutledge v. PCMA*, the Court held that ERISA did not preempt 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. Unlike the PBM laws in some states, Act 900 was not strictly structured as an insurance law. It applied to all transactions between PBMs and pharmacies, including transactions where the PBM was acting on behalf of a self-insured ERISA plan, so Arkansas could not rely on the saving clause as its defense against an ERISA preemption challenge.

In a suit brought by Pharmaceutical Care Management Association (“PCMA”), a national trade association representing 11 PBMs, the Eastern District of Arkansas 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, concluded that “[t]he logic of *Travelers* decides this case,”⁵ and ruled that Act 900 was not preempted by ERISA. The Court compared its decisions in *Gobeille*, where it held that a state law is preempted if it “governs a central matter of plan administration or interferes with nationally uniform plan administration,”⁶ and *Travelers*, where it held that ERISA does not preempt state price regulations that “merely increase costs or alter incentives for ERISA plans without forcing plans to adopt any particular scheme of substantive coverage,”⁷ even if the law “affects an ERISA plan or causes some disuniformity in plan administration.”⁸ The Court explained that ERISA is “primarily concerned with preempting laws that require ... structure[ing] benefit plans in particular ways, such as by requiring payment of specific benefits, or by binding plan administrators to specific rules for determining beneficiary status. A state law may also be subject to pre-emption if ‘acute, albeit indirect, economic effects of the state law force an ERISA plan to adopt a certain scheme of substantive coverage.’”⁹ The Court observed that Act 900 “does not require plans to provide any particular benefit to any particular

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.

⁶ *Id.* at 480, quoting *Gobeille*, 577 U.S. at 320.

⁷ *Id.* at 480, citing *Travelers*, 514 U.S. at 668.

⁸ *Id.*

⁹ *Id.*, quoting *Gobeille*, 577 U.S. at 320.

beneficiary in any particular way,”¹⁰ and determined that like the law at issue in *Travelers*, “Act 900 is merely a form of cost regulation.”¹¹

The Court reviewed the standards it has established for interpreting ERISA’s preemption clause, which preempts all state laws “insofar as they ... relate to any employee benefit plan”¹² unless some exception to preemption applies. The Court explained that a state law triggers the preemption clause when it “has a connection with or reference to” an ERISA plan.¹³ 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.”¹⁴ The Court acknowledged that Act 900 required ERISA plan administrators to “comply with a particular process” and standards,¹⁵ 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.¹⁶ 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.¹⁷

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.¹⁸

However, the Court only considered the provisions of the Arkansas PBM law as they stood at the time PCMA filed its preemption challenge, not the amendments the legislature subsequently made while *Rutledge* was making its way through the appellate courts. Additionally, the Court did not address preemption under Medicare Part D and issues that have been raised by PBM and pharmacy laws in other states, including laws regulating provider networks and laws addressing contractual restrictions on discussions between pharmacies and patients. Subsequent to the *Rutledge* decision, additional ERISA challenges continue, at the time of this writing, to make their way through the courts.

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¹⁰ *Id.* at 482.

¹¹ *Id.* at 481.

¹² 29 U.S.C. § 1144(a).

¹³ 141 S.Ct. at 477.

¹⁴ *Id.* at 481–482.

¹⁵ *Id.* at 482, quoting PCMA brief at 24.

¹⁶ *Id.*

¹⁷ *Id.*

¹⁸ *Id.* at 481.

Draft Pending Adoption

Attachment Seven
Regulatory Framework (B) Task Force
8/10/22

Draft: 4/27/22

Mental Health Parity and Addiction Equity Act (MHPAEA) (B) Working Group
Kansas City, Missouri
April 5, 2022

The MHPAEA (B) Working Group of the Regulatory Framework (B) Task Force met in Kansas City, MO, April 5, 2022. The following Working Group members participated: Erica Weyhenmeyer, Chair (IL); Jane Beyer, Vice Chair, and John Haworth (WA); Damion Hughes (CO); Kurt Swan (CT); Kenneth Scott and Barbara Torkelson (KS); Mary Kwei (MD); Paul Hanson (MN); Cynthia Amann and Carrie Couch (MO); David Dachs (MT); John Arnold and Chrystal Bartuska (ND); Laura Arp (NE); Maureen Belanger (NH); Laura Miller (OH); Landon Hubbart (OK); Shannen Logue and Katie Merritt (PA); Chris Herrick (TX); Ryan Jubber and Tanji J. Northrup (UT); Don Beatty and Julie Fairbanks (VA); Erin K. Hunter (WV); and Bryce Hamilton (WY).

1. Heard a Presentation on the Development of a Designation in Mental Health Parity by the IRES

Ms. Weyhenmeyer and Mr. Haworth presented on a new designation from the Insurance Regulatory Examiners Society (IRES). Ms. Weyhenmeyer provided background on the IRES and said it has a goal of creating a consistent approach in behavioral health parity audits. Mr. Haworth said the IRES plans to develop core classes for the designation. Core 1 would be the history of state and federal laws and regulations on mental health parity. Core 2 would describe the requirements around quantitative treatment limits (QTLs) and non-quantitative treatment limits (NQTLs). Core 3 would look at medical necessity and utilization review. Core 4 would be a catch-all that looks at claims coding, network access and adequacy, and vendor oversight. Mr. Haworth said supplemental courses would examine criteria for treatment from the American Society of Addiction Medicine (ASAM), quality assessments, and newer state laws. Ms. Weyhenmeyer said the current focus is on the initial core courses, and the intent is to offer some of them in the career development seminar in August or September. Mr. Haworth said ASAM criteria is an example, but the designation would include other criteria as well.

2. Heard a Presentation on Mental Health Parity Enforcement by the DOL

Amber Rivers (U.S. Department of Labor Employee Benefits Security Administration—DOL EBSA) presented on activity on mental health parity enforcement on private employment-based health plans. She said enforcement of the federal Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA) and the new provisions under the Consolidated Appropriations Act, 2021 is a top priority for the EBSA. She said plans are now required to document their compliance with mental health parity, and the DOL is required to collect comparative analyses and report its findings to the U.S. Congress (Congress). She said the new tools have been important in encouraging plans to take the requirements seriously. She said the DOL has released guidance and responded to questions before asking for documentations from plans. She said the substance of mental health parity rules has not changed, so all previous guidance from federal agencies is still applicable; what has been added is a requirement to document compliance.

Ms. Rivers said the DOL has released a report to Congress on its enforcement. She said the report shows the actions the DOL has taken and what it has received from plans. She said NQTLs are complex to analyze, and the DOL has highlighted interest in four areas: 1) prior authorization; 2) concurrent review; 3) admission into plan networks; and 4) out-of-network reimbursement rates. She said the report documents 156 letters requesting analyses of 216 NQTLs across 86 investigations. She said many plans and issuers were unprepared to provide analyses. They were missing key information that was outlined in previously published frequently asked questions

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(FAQ). Ms. Rivers said the DOL has issued over 30 findings of parity violations. She said plans may submit a corrective action plan when they are found not compliant. She said the next report will come in October. She said the DOL plans a proposed rule on the MHPAEA.

3. Heard a Presentation on Documenting Compliance with NQTLs

Tim Clement (American Psychiatric Association—APA) presented a sample comparative analysis to demonstrate how a health plan could document that one of its NQTLs complies with mental health parity regulations. He said health plans often hear that their analyses did not hit the mark for what is required. He said his example would be a focus on concurrent review.

Mr. Clement said comparative analyses do not need to be lengthy; rather, being concise is a virtue. He said there are five steps in his example based on the provisions of the MHPAEA statute. He said step one includes definitions of terms used. He said step two covers the factors that determine when concurrent review occurs. He described step three as explaining in more detail how each factor is applied, and it could include supporting data to show that the plan has calculated data appropriately. He said the comparative analysis should be self-contained, and attachments should offer verifying proof in support rather than take the place of the analysis itself. He described how the analysis could demonstrate the factors it applies through data or a chosen rationale. He said all factors should be covered in the analysis, as well as all evidence and sources. He said this step should list sources, which should be explained more fully in step four.

Mr. Clement said step four has the most content. He said the analysis must demonstrate that processes and strategies are no more restrictive for mental health and substance use disorder (MU/SUD) benefits than for medical and surgical (M/S) benefits. He said state insurance regulators should not be unsure whether the standard has been met after reading step four. He said the analysis should discuss the plan's utilization management manual in step four. This discussion establishes whether processes and strategies are the same or no more restrictive as written. Mr. Clement said processes in operation must also be analyzed. He said the analyses should describe first and second level utilization reviews rather than appeals. He said analyses should show that some review occurred to demonstrate that processes meet parity in operation. He said the necessary analysis is at the process level and should show how and why processes are comparable. He said step five should review all the previous steps and show how they lead to a conclusion of parity compliance.

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

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Attachment Eight
Regulatory Framework (B) Task Force
8/10/22

Draft: 8/17/22

Pharmacy Benefit Manager Regulatory Issues (B) Subgroup
Portland, Oregon
August 9, 2022

The Pharmacy Benefit Manager Regulatory Issues (B) Subgroup of the Regulatory Framework (B) Task Force met in Portland, OR, Aug. 9, 2022. The following Subgroup members participated: TK Keen, Chair (OR); Laura Arp, Vice Chair, and Eric Dunning (NE); Sarah Bailey (AK); Jimmy Dunn, Reyn Norman, and Sheila Travis (AL); Crystal Phelps (AR); Paul Lombardo and Mike Shanahan (CT); Howard Liebers (DC); Andria Seip (IA); Vicki Schmidt and LeAnn Crow (KS); Daniel McIlwain and Rob Roberts (KY); Chad Arnold (MI); T.J. Patton (MN); Amy Hoyt (MO); Mary Belcher (MT); Robert Croom (NC); Ralph Boeckman and Erin Porter (NJ); Paige Duhamel (NM); Kelli Price (OK); Karen Feather (PA); Melissa Manning (SC); Scott McAnally and Brian Hoffmeister (TN); Tanji J. Northrup (UT); Don Beatty (VA); Jennifer Kreitler and Molly Nollette (WA); Nathan Houdek and Jennifer Stegall (WI); Allan McVey and Jamie Taylor (WV); and Bryce Hamilton (WY). Also participating were: Weston Trexler (ID); Paul Meyer (MD); and Larry D. Deiter (SD).

1. Adopted its July 29, June 15, April 25, and Spring National Meeting Minutes

The Subgroup met July 29, June 15, April 25, and April 4. During these meetings, the Subgroup heard presentations from various stakeholders on issues from their perspective on the Subgroup's 2022 charge to develop a white paper on pharmacy benefit manager (PBM) business practices.

Mr. Lombardo made a motion, seconded by Mr. Roberts, to adopt the Subgroup's July 29 (Attachment Eight-A), June 15 (Attachment Eight-B), April 25 (Attachment Eight-C), and April 4 (Attachment Eight-D) minutes. The motion passed unanimously.

2. Heard a Presentation from the PCMA

Peter Fjelstad (Pharmaceutical Care Management Association—PCMA) discussed the value of PBMs and the services they provide with respect to pharmacy benefit management. He said PBMs are committed to helping patients. PBMs are the only entity in the pharmaceutical supply chain advocating for lower prescription drug costs for patients and payers. He explained that the plan sponsor is the PBM's client, who always has the final say when creating and designing a prescription drug benefit plan to include elements such as formulary management, specialty and mail order pharmacies, preferred pharmacy networks, and negotiation of rebates. There is no one-size-fits all model because each plan sponsor has unique needs.

Mr. Fjelstad outlined the plan sponsor request for proposal (RFP) process and how PBMs bid in this competitive process by offering various design models and compensation terms, depending on the plan sponsor's specific needs. He detailed the types of pharmacy benefit management services PBMs can provide to plan sponsors. He also discussed the tools PBMs use to reduce prescription drug costs for patients and payors, which include: 1) negotiating rebates from prescription drug manufacturers; 2) reducing waste; 3) encouraging use of generics and preferred brand name drugs; 4) improving adherence; and 5) managing high-cost specialty medications. Mr. Fjelstad said that research shows that the current use of these PBM tools will save plan sponsors and consumers more than \$1 trillion in prescription drug costs from 2020 to 2029. He discussed the results of a 2020 survey of company benefit managers and human resource directors indicating high satisfaction with their

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company's PBM, PBM contract transparency, and the PBM's effectiveness in reducing prescription drug costs for their company.

Mr. Fjelstad discussed a PBM's role in the pharmaceutical supply chain. He suggested that the Subgroup examine and identify in the white paper the role each entity plays in the pharmaceutical supply chain. He said the pharmaceutical drug manufacturer is the only entity in the supply chain that sets the list price of drugs. He also said that an analysis of data from 2016 to 2020, published in January 2022, indicates that manufacturer prescription drug price increases are unrelated to PBM negotiated rebates.

Mr. Fjelstad highlighted how PBM technology and expertise helps patients to lead healthier lives. PBMs administer prescription drug benefits for 266 million Americans, which means immediate access to the right prescription drugs at the right time and place for thousands of patients each day. PBMs continue to innovate, providing information on cost-sharing and drug coverage through real-time benefit tool (RTBT) access to 82% and electronic approval coverage for drugs that need authorization to 98% of patients who have coverage through contracted health plans and PBMs. He said PBMs are also developing technology to directly engage with patients and enhance their lives, which not only improves clinical outcomes, but also gives patients greater control over their own health.

Commissioner Schmidt asked Mr. Fjelstad about PBM vertical integration with PBMs owning pharmacies and concerns that because of such market consolidation, there is less transparency about PBM business practices. She also noted that the statistics cited during the presentation did not include any statistics on independent community pharmacist satisfaction with PBMs, which would probably show a much different level of satisfaction as compared with the level of satisfaction indicated for company benefit managers and human resource directors. Mr. Fjelstad said there is more of an adversarial relationship between independent community pharmacists and PBMs than perhaps other entities in the pharmaceutical supply chain. He said that about 83% of independent community pharmacies use pharmacy services administrative organizations (PSAOs), which are large conglomerates, to negotiate their contracts with PBMs on their behalf. Therefore, it is not like these pharmacies do not have any leverage or are mismatched in their business dealings with PBMs. He said with respect to vertical integration, the health care industry has seen a lot of integration whether it be PBMs and health insurers owning PBMs and a chain of retail pharmacies. He said increased state and federal regulatory requirements since the enactment of the federal Affordable Care Act (ACA) has led to smaller independent community pharmacies going out of business because they do not necessarily have the expertise, time, or manpower to keep up with these regulatory compliance requirements, such as those involved in dispensing prescription drugs under the federal 340B program. He said this is a factor in the market consolidation among the entities in the pharmaceutical supply chain. Commissioner Schmidt disagreed with Mr. Fjelstad's argument that independent community pharmacies lack the expertise necessary to stay in business due to increased regulatory requirements and competition with large "big box" chain pharmacies.

Mr. Beatty said that statistics are not needed to know that there is tension between independent community pharmacists and PBMs. He asked Mr. Fjelstad about the actions the PCMA, on behalf of the PBM industry, could do voluntarily to alleviate this tension without involving state and federal regulators. Mr. Fjelstad suggested that meetings such as this meeting on the local and state level where all the stakeholders are participating would help alleviate such tensions. Mr. Lombardo asked about spread risk pricing and the recent enactment in some states prohibiting it and the impact, if any, on PBM revenue, when spread risk pricing is eliminated. Mr. Fjelstad said he would be happy to follow up with Mr. Lombardo regarding his specific question. He said, generally, in a spread risk pricing model, or risk mitigation model, the PBM takes the risk to either lose money or gain a profit or a margin. However, which risk mitigation model is chosen depends on the plan sponsor. The plan sponsor decides

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whether it wants to use a pass-through model where rebates are shared with specific entities or a spread risk pricing model. He said he believes that the PBM industry's position on this issue is that the states should not intrude on the private contractual negotiations between the plan sponsor and the PBM. Mr. Lombardo said his concern with eliminating spread pricing, which would increase the payments to pharmacies and allow PBMs to increase their administrative fees to make up lost revenue, is that it would add cost to the pharmaceutical distribution system. As such, he would appreciate follow-up information on what actions PBMs are taking, if any, in response to the elimination of spread risk pricing.

3. Heard a Presentation from the PhRMA on Issues Related to the Lack of Transparency in PBM Practices

Emily Donaldson (Pharmaceutical Research and Manufacturers of America—PhRMA) discussed issues related to the lack of transparency in PBM practices. She explained that this lack of transparency has led to misaligned incentives, which can cause an increase in costs throughout the health care system. She said that there is evidence that shows one such misaligned incentive appears to provide PBMs incentives to prefer medicines with higher list prices and large rebates. She discussed how PBMs have increased their influence in the pharmaceutical supply chain through horizontal and vertical consolidation.

Ms. Donaldson said a large—and growing—share of the rebates paid by manufacturers are not being used to reduce patient costs at the pharmacy counter. She provided an example of how consumers do not directly benefit from the rebates and discounts with respect to prescription drugs unlike the direct benefits consumers receive with respect to medical services. She said consumers can end up paying a greater share of total cost for their prescription drugs than their health insurers.

Ms. Donaldson discussed policy solutions to address misaligned incentives in the pharmaceutical supply chain. She suggested these policy solutions: 1) anti-steering policies prohibiting PBMs from directing patients to affiliate pharmacies, which would improve competition and reduce incentives for PBMs to self-deal; 2) sharing rebates at the point-of-sale; and 3) “delinking” PBM compensation from the price of medicines, which would prevent PBMs from skirting regulation on rebates.

4. Heard a Presentation from the OPCA on the Federal 340B Prescription Drug Program

Marty Carty (Oregon Primary Care Association—OPCA) discussed the federal 340B prescription drug program. He said the program began in 1992 and requires pharmaceutical manufacturers to sell drugs at a discount to “covered entity” providers. These providers include federally qualified health centers (FQHCs), Ryan White clinics, and disproportionate share hospitals (DSHs). Mr. Carty outlined the 340B program requirements for participants, which include: 1) registration and recurring recertification; 2) subject to federal audits; 3) must work to avoid duplicate discounts on a single drug; and 4) ensure appropriate use of 340B program savings. He highlighted how the 340B program has assisted two entities, the Neighborhood Health Center and the Siskiyou Community Health Center, in enhancing and enabling them to provide much needed assistance to patients by covering the cost of prescription medications, medical and dental care, food, and transportation.

Mr. Carty discussed how in 2016–2017 community health centers began fighting state-by-state to retain 340B savings on prescription drugs reimbursed under Medicaid managed care and how this so-called “pick-pocketing” continues to expand rapidly. He said to combat these actions, states began enacting 340B anti-discrimination legislation. He said 22 states prohibit PBMs from: 1) refusing to contract with 340B program participating providers; 2) reimbursing at a lower amount; 3) imposing different fees; and 4) otherwise discriminating against

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a 340B covered entity. He asked that the state insurance regulators use the tools available to them to protect the 340B program.

Director Dunning asked about rebates and the 340B program, particularly any rebates paid back to those patients receiving services from an FQHC who are commercially insured. Mr. Carty said he does not have information about commercially insured patients. He said a majority of those receiving services through an FQHC are either uninsured or Medicaid recipients. Mr. Carty agreed to follow up with any information he might have about rebates and patients receiving services through a FQHC who are commercially insured.

Commissioner Schmidt said she has worked with FQHCs and the 340B program and appreciates the work that they do. She said she believes the Subgroup should discuss the issues Mr. Carty raised with respect to discriminatory pricing that some 340B program participating providers have experienced.

Mr. Keen asked Mr. Carty that because enforcement of the anti-discrimination laws that have been enacted rests with state insurance regulators, if he was aware of any enforcement actions taken by the states. Mr. Carty said he is not aware of any such actions, but he would follow up with Mr. Keen after he does some research. Ms. Seip asked Mr. Carty if he had any examples of discriminatory pricing and what that contract language would look like that he could share with the Subgroup. Mr. Carty said he would follow up with Ms. Seip to provide such examples.

5. Discussed Next Steps

Mr. Keen said he anticipates the Subgroup meeting within the next few weeks to complete its work on hearing from various stakeholders on issues from their perspective on the Subgroup's 2022 charge to develop a white paper examining PBM business practices. He said that he also anticipates during this meeting a discussion of the implications, if any, of a provision in the federal Inflation Reduction Act of 2022 allowing Medicare to negotiate for prescription drug prices.

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

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Draft: 8/2/22

Pharmacy Benefit Manager Regulatory Issues (B) Subgroup
Virtual Meeting
July 29, 2022

The Pharmacy Benefit Manager Regulatory Issues (B) Subgroup of the Regulatory Framework (B) Task Force met July 29, 2022. The following Subgroup members participated: TK Keen, Chair (OR); Laura Arp, Vice Chair, and Eric Dunning (NE); Kayla Erickson (AK); Anthony L. Williams (AL); Kathy Belfi and Michael Shanahan (CT); Howard Liebers (DC); Andria Seip (IA); Vicki Schmidt (KS); Sharon P. Clark and Daniel McIlwain (KY); Jeff Zewe (LA); Joe Stoddard (MI); Chlora Lindley-Myers and Cynthia Amann (MO); Andrew Kleinendorst and Victoria Bares (MN); David Dachs (MT); Tracy Biehn (NC); Erin Porter and Ralph Boeckman (NJ); Paige Duhamel (NM); Kelli Price (OK); Ana Paulina Gomez (PA); Maggie Rosa (SC); Scott McAnally and Brian Hoffmeister (TN); Tanji J. Northrup (UT); Don Beatty (VA); Jennifer Kreitler and Ned Gaines (WA); Jennifer Stegall (WI); Jamie Taylor (WV); and Bryce Hamilton (WY). Also, participating were: Paula Shamburger (GA); and Emily Brown (VT).

1. Discussed Questions on NCPA Presentation

As a follow-up from its June 15 meeting, the Subgroup held a question and answer (Q&A) session on the National Community Pharmacists Association (NCPA) presentation. Ms. Price asked Matthew Magner (NCPA) if the NCPA would be in favor of state laws that require pharmacy benefit managers (PBMs) to reimburse pharmacies for filling prescriptions in amounts at or above the pharmacy acquisition costs, or has the NCPA found that such laws make it difficult for pharmacies and pharmacy services administrative organizations (PSAOs) to negotiate with PBMs with respect to other contract provisions. Mr. Magner said the NCPA has been supportive of a reimbursement benchmark. He discussed recent legislation enacted in West Virginia that the NCPA believes is a good example of a reimbursement benchmark. Mr. Keen asked about higher reimbursement and dispensing fees and the ultimate impact, if any, on consumers and/or end users. Mr. Magner said the NCPA believes the key issue is the lack of transparency in reimbursement. A pharmacist does not know how much he or she will ultimately be reimbursed even after a claim has been adjudicated because of retroactive clawbacks months later. Mr. Magner said that for consumers in the deductible phase, the amount the consumer pays at the counter for a prescription drug is based on the pharmacy's reimbursement amount for that drug, which does not account for any retroactive clawbacks. As such, the consumer is paying an inflated amount. He said that again, the key to address this issue is transparency.

2. Heard a Presentation on the Pharmaceutical Distributor Perspective

Will Dane (Healthcare Distribution Alliance—HDA) presented on a pharmaceutical distributor perspective on issues related to the Subgroup's 2022 charge to develop a white paper to: 1) analyze and assess the role PBMs, 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 v. 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. He provided background on the HDA, including its role, since its founding in 1876, in helping its members navigate regulations and innovations to get the right medicines to the right patients at the right time, safely and efficiently. The HDA's members include 35 national, regional, and specialty primary distribution companies constantly envisioning new ways to move and secure the nation's medicines, all while protecting patient safety. Mr. Dane described the pharmaceutical distribution system, highlighting the role pharmaceutical distributors play in the supplying

prescription drugs nationwide. He also illustrated what the prescription drug supply chain would look like with and without pharmaceutical distributors.

Mr. Dane summarized the role pharmaceutical wholesale distributors play in the prescription drug supply chain as follows: 1) distributors purchase health care products from manufacturers based on the wholesale acquisition cost (WAC), which manufacturers set; 2) distributors charge manufacturers fees related to their services, which are not passed on to the customer nor do they affect patients' cost; 3) distributors sell brand medications to providers based on the WAC or WAC minus a certain percentage; and 4) for generic drugs, since they are commodities, distributors can negotiate prices typically below manufacturer WACs in exchange for sourcing certain generic drugs solely from one source or from a few specified sources. He also provided an example of supply chain profits. He explained that pharmaceutical wholesale distributors primarily use a fee-for-service model. He added that the pharmaceutical distribution model is a high-value, high-volume but low-profit margin industry. Mr. Dane said a recent analysis from Berkeley Research Group (BRG) shows the profit margin for a wholesaler is approximately 1% of the cost of brand medicines.

Ms. Brown asked Mr. Dane if providers typically purchase pharmaceuticals from one distributor. Mr. Dane said it varies depending on the type of provider, such as, for example, an independent community pharmacy versus a hospital. Mr. Hamilton asked about the extent of vertical integration between manufacturers and wholesale distributors. Mr. Dane said none. He described different approaches some wholesalers have taken regarding pharmaceuticals, such as creating repackaging and relabeling businesses, but he noted that these businesses would not be thought of as manufacturers and as such, this would not be considered vertical integration.

3. Heard Presentation on the PSAO Perspective

Scott Pace (Impact Management Group) provided the PSAO perspective on issues related to the Subgroup's 2022 white paper charge. He discussed the role and value of PSAOs. PSAOs are service organizations that provide back-office support to independent community pharmacies and small chains, including services such as: 1) evaluation and navigation of PBM contracts; 2) help desk to assist pharmacies with communications with the PBMs; 3) credentialing and compliance assistance; 4) central payment facilitation; and 5) PBM audit support. For providing such services, PSAOs charge a flat monthly fee.

Mr. Pace explained who PSAOs are. He said that in a 2013 report, the Government Accountability Office (GAO) identified 22 PSAOs owned by a mix of wholesalers, PSAO-member pharmacies, group purchasing organizations, and other private entities. Today, it is estimated there are fewer than 10 PSAOs in operation. He said that according to one analysis, it is estimated that in 2021, the six largest PSAOs had 1,700 to 6,800 participating independent pharmacies each, with a median of 4,250 per PSAO. He said that in comparison with PBMs, the percentage of total U.S. prescription claims managed by the six largest PBMs in 2018 was 95%. The top three PBMs control 77% percent of the prescription market, and the second largest PBM accounts for approximately 90 million plan members and controlled 68,000+ pharmacies.

Mr. Pace explained that independent community pharmacies and/or small chains often do not have the infrastructure and expertise of their larger chain competitors. He said that as a result, some choose to contract with a PSAO to assist with managing their PBM interactions and "back-office" administrative duties. He described the scope of these services, including services a PSAO does not provide, such as: 1) dictating reimbursement rates; 2) setting maximum allowable cost (MAC) rates; 3) retaining any portion of the pharmacy reimbursement; and 4) creating direct or indirect remuneration (DIR) fees.

Mr. Pace provided a summary of the current landscape with respect to state policy trends and understanding of PSAOs, including misunderstandings of the services PSAOs provide and their role. He suggested that the states

when considering legislative proposals involving PSAOs, they should consider the PSAO perspective and its actual role. He also advocated the idea that “if it ain’t broke, don’t fix it.” He said PSAOs are not PBMs or insurers and should not be treated as such. He also suggested that the states remember the actual role of PSAOs and that PSAOs do not notably affect the cost of medication. PSAOs also are not responsible for patient benefit design. Mr. Pace said PSAOs are administrative support service providers. He also said not all PSAOs are wholesale distributor-owned, and not all wholesalers operate a PSAO business. He said who owns a PSAO does not affect market influence or prices. In summarizing his presentation, Mr. Pace said: 1) PSAOs are administrative service entities that charge a transparent flat fee for their services; 2) PSAOs assist with executing contracts; they do not negotiate with manufacturers, determine medication costs, nor sell medications to pharmacies; 3) pharmacies engage PSAOs to provide administrative support and expertise so pharmacists can focus on serving their patients; and 4) PSAOs do not affect the cost of pharmaceutical drug products and have no role in health benefit plan formulary design.

Ms. Duhamel asked if PSAOs file MAC appeals on behalf of pharmacies. Mr. Pace said sometimes PSAOs have filed such appeals on behalf of pharmacies. He said pharmacies like PSAOs to make such filings, but PBMs have been reluctant to accept appeals from PSAOs. He also said the reluctance of PBMs to accept MAC appeals from PSAOs is easing because some states have passed laws allowing PBMs to accept MAC appeals made on behalf of pharmacies from PSAOs. Mr. McAnally asked about the payment timeline. Mr. Pace said payment terms are usually described in the contract. He explained that in Arkansas, for Medicaid fee-for-service claims, his pharmacy is paid around seven days after the filing a claim. For other types of plans, his pharmacy is paid around 15 days after filing a claim. He noted that some states have enacted prompt pay laws that apply to pharmacy claims that set a maximum time within which a claim is to be paid. Mr. Pace noted that these reimbursements do not account for retroactive clawbacks or so-called “true ups” occurring months after the initial claim has been paid. Mr. Pace also discussed “true up” process and aggregate payments based on the effective rate. He said that a few states, including Arkansas, prohibit the use of effective rates.

Mr. Hamilton asked about vertical integration in the PSAO industry. Mr. Pace said he would consider such integration to fall into two buckets: 1) wholly owned affiliates, which is a PSAO owned by a pharmaceutical wholesaler; and 2) stand-alone entities, some of which are owned by group purchasing organizations. He said from a payment perspective, whether it is a wholly owned affiliate or a stand-alone entity, there is not much of a difference in the reimbursement rates a pharmacy receives. Ms. Shamburger asked about PSAOs’ regulatory compliance and credentialing services. Mr. Pace said one example of this would be the excluded provider list. Prescribers on this list are not eligible to write prescriptions and receive reimbursement under Medicare. He said PSAOs provide pharmacies with updated excluded provider lists on a weekly or monthly basis, which assists pharmacies with regulatory compliance.

Mr. Dachs asked if in Mr. Pace’s experience, in negotiating contract terms with PBMs, does negotiating on behalf of a larger number of pharmacies provider better leverage than negotiating on behalf of one pharmacy. Mr. Pace said that based on his experience, it makes no difference. He said, however, that for contract terms involving non-payment issues, such as audit practices and timelines, he believes PSAOs are better able to negotiate than an individual pharmacy can. Mr. Hamilton asked if pharmaceutical manufacturers are purchasing entities further down the prescription drug supply chain in an effort to possibly maintain their lists prices. Mr. Pace said he is not aware of this. He said that based on his experience, pharmaceutical manufacturers are moving in the opposite direction away from direct purchasers of the product.

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

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Draft: 7/14/22

Pharmacy Benefit Manager Regulatory Issues (B) Subgroup
Virtual Meeting
June 15, 2022

The Pharmacy Benefit Manager Regulatory Issues (B) Subgroup of the Regulatory Framework (B) Task Force met June 15, 2022. The following Subgroup members participated: TK Keen, Chair (OR); Laura Arp, Vice Chair (NE); Kayla Erickson (AK); Anthony L. Williams, William Rogers, and Jimmy Gunn (AL); Beth Barrington (AR); Jessica Ryan (CA); Kathy Belfi, Mike Shanahan, and Paul Lombardo (CT); Howard Liebers (DC); Andria Seip (IA); Vicki Schmidt, Tate Flott, Craig Van Aalst, and Julie Holmes (KS); Daniel McIlwain (KY); Jeff Zewe (LA); Chad Arnold and Joe Stoddard (MI); Amy Hoyt (MO); Andrew Kleinendorst and Galen Benshoof (MN); David Dachs (MT); Ted Hamby and Robert Croom (NC); Erin Porter and Ralph Boeckman (NJ); Renee Blechner (NM); Kelli Price (OK); Mike Humphreys and Ana Paulina Gomez (PA); Katrina Rodon (SC); Scott McAnally (TN); Shelley Wiseman (UT); Don Beatty (VA); Ned Gaines (WA); Jennifer Stegall (WI); Michael Malone (WV); and Jeff Rude and Bryce Hamilton (WY).

1. Heard a Presentation from the NCPA Discussing its Perspective on the Subgroup's Charge to Develop a Whitepaper

Matthew Wagner (National Community Pharmacists Association—NCPA) discussed the independent community pharmacists' perspective on issues related to the Subgroup's 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.

Mr. Wagner provided a profile of independent community pharmacists and pharmacies. He said there are 19,400 independent community pharmacies nationwide. Of these pharmacies, approximately 80% are in areas with populations of less than 50,000 people. He said that in such areas and underserved areas, residents consider independent community pharmacists as essential health care providers and local health care problem solvers because they are the only health care providers available to them. He discussed the current business climate for independent community pharmacies and its impact on their ability to contract with PBMs. He said having three PBMs control as much as 80% of the market and the role of PSAOs in the contracting process are key factors independent community pharmacies face in contracting with PBMs. Mr. Wagner suggested that such a business climate and other issues—such as the conflicts of interest in the prescription drug supply and distribution chain due to increased consolidation and integration, rising prescription drug costs, and a lack of accountability—is why regulatory oversight of PBMs is necessary. He discussed state efforts to regulate PBMs, including state PBM licensing and registration laws, state laws prohibiting mandatory mail-order, and state laws addressing reimbursements to PBM-affiliated entities.

Mr. Wagner described some of the drawbacks in state PBM laws, such as overly broad exclusions and exemptions for Employee Retirement Income Security Act of 1974 (ERISA) plans and Medicare Part D plans, which create obstacles to reform. He pointed out guidance from federal courts on ERISA preemption in recent rulings, such as the U.S. Supreme Court's ruling in *Rutledge* and federal circuit courts of appeal rulings in the *PCMA v. Wehbi* case and the *PCMA v. Mulready* case. He said another obstacle to reform are restrictions placed on the ability of pharmacists to alert state departments of insurance (DOIs) or other regulatory authorities about PBM business

practices that potentially conflict with state laws. He said such restrictions include state laws that only allow a state DOI to accept complaints from a consumer. Mr. Magner also said pharmacists are afraid to complain because they fear retaliation by PBMs through audits and increased scrutiny. He said another obstacle to reform related to state laws is whether the state law applies to the insurer or the PBM and whether the state law applies to plans that originate out of state. He said contractual and definitional loopholes in some state laws are also problematic. Mr. Magner urged the Subgroup to highlight these issues in the white paper to make states aware of these issues and potentially address them.

The Subgroup ran out of time for questions and agreed to invite Mr. Magner back for a question-and-answer session during one of the Subgroup's future meetings.

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

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Draft: 5/12/22

Pharmacy Benefit Manager Regulatory Issues (B) Subgroup
Virtual Meeting
April 25, 2022

The Pharmacy Benefit Manager Regulatory Issues (B) Subgroup of the Regulatory Framework (B) Task Force met April 25, 2022. The following Subgroup members participated: TK Keen, Chair (OR); Eric Dunning, Vice Chair (NE); Sarah Bailey and Kayla Erickson (AK); Beth Barrington (AR); Jessica Ryan (CA); Paul Lombardo (CT); Howard Liebers (DC); Andria Seip (IA); Tate Flott (KS); Sharon P. Clark and Daniel McIlwain (KY); Jeff Zewe (LA); Chad Arnold and Joe Stoddard (MI); Amy Hoyt (MO); Andrew Kleinendorst, Galen Benshoof, and Norman Barrett Wiik (MN); Troy Downing and David Dachs (MT); Ted Hamby and Robert Croom (NC); Erin Porter (NJ); Renee Blechner (NM); Glen Mulready and Kelli Price (OK); Ana Paulina Gomez (PA); Carlos Valles (PR); Maggie Rosa (SC); Brian Hoffmeister and Scott McAnally (TN); Heidi Clausen (UT); James Young (VA); Jennifer Kreidler and Ned Gaines (WA); Jennifer Stegall (WI); Ellen Potter (WV); and Jeff Rude and Bryce Hamilton (WY). Also participating were: Amy L. Beard (IN); Paul Meyer (MD); and Eamon G. Rock (NY).

1. Heard Presentation on PBM Markets

Neeraj Sood (University of Southern California [USC], Shaeffer Center for Health Policy & Economics) and Karen Van Nuys (USC, Shaeffer Center for Health Policy & Economics) presented on “How Well Are PBM Markets Functioning?” Dr. Van Nuys discussed the flow of money through the pharmaceutical distribution system, which is further detailed in a 2017 research paper *The Flow of Money Through the Pharmaceutical Distribution System*, co-authored by Dr. Sood and others. She said Dr. Sood discussed this in his presentation to the Subgroup a few years ago, but she wanted to refresh the Subgroup’s memory on this subject and then provide an update on what she and Dr. Sood are currently researching related to this topic.

Dr. Van Nuys explained that at the time the research paper was published in 2017, the researchers could only examine the flow of money through the pharmaceutical distribution system for prescription drugs in the aggregate. The researchers could not single out one specific prescription drug in following the flow of money and determining the amount of money each entity along that system captured from a typical expenditure. Dr. Van Nuys said that based on this, the natural question to ask is whether the amount of money captured by some of the intermediaries along the distribution system is excessive. She said that determining whether the amount of money being captured is excessive depends, in part, on the level of risk that entity is taking to participate in the distribution system. She said Dr. Sood, along with other researchers, published a research article in January 2021 examining this question. She described the methodology used to estimate so-called “excess returns,” which is the extent to which an entity’s profits are higher than expected given the risk associated with their investments, for manufacturers, and intermediaries in the pharmaceutical supply chain to determine who is making excessive profits. She said the researchers’ findings suggest that: 1) there are excess returns in the distribution system and amongst prescription drug manufacturers and biotech manufacturers; and 2) there are potentially certain public policies, which promote competition in all areas of the pharmaceutical supply chain, that could curtail prescription drug spending. Dr. Sood noted that some aspects of the research into this question were limited due to the fact of vertical integration in the system—insurers owning pharmacies and other such consolidation in the distribution system.

Dr. Van Nuys next discussed current research as a result of changes since 2017, when the first research paper she discussed was published, which allowed researchers, such as herself and Dr. Sood, to analyze the flow of money along the pharmaceutical distribution system for specific drugs, such as diabetes drugs. One example of such a change was the enactment of state laws requiring prescription drug manufacturers to disclose certain financial

information. She referenced a Nevada law that requires such disclosure for diabetes drugs, including insulin, and a report from the Ohio Auditor of State examining the state's Medicaid managed care pharmacy services and spread pricing within the program. Dr. Van Nuys discussed the methodology, including the meanings of "list price," "net price," and "net expenditure." She also discussed findings from a research paper published in the Journal of the American Medical Association (JAMA) Health Forum in November 2021 titled "Estimation of the Share of Net Expenditures on Insulin Captured by U.S. Manufacturers, Wholesalers, Pharmacy Benefit Managers, Pharmacies, and Health Plans from 2014 to 2018," which she co-authored with Dr. Sood and other researchers that uses this new data resource to examine the money flows from insulin distribution.

Dr. Sood discussed preliminary research and findings related to the Medicare Part D market and the issue of vertical integration and market consolidation. He explained that the research in this area is continuing and as such, it has not been published. He said he hopes to be able to publish sometime in the near future. He discussed three insurer-pharmacy benefit manager (PBM) relationships: 1) in-house, where the insurer uses its own PBM—for example, CVS. This PBM also provides PBM services to other insurers; 2) rival PBMs, where the insurer uses a PBM owned by a rival health plan—for example, HealthNet contracting with CVS; and 3) standalone PBM, where the insurer uses a PBM that is not owned by a health plan, such as Catamaran, which no longer exists because it was acquired by UnitedHealthcare. Dr. Sood explained that the last insurer-PBM relationship no longer exists in the Part D market. There are no stand-alone PBMs. He discussed how the market has evolved over time with in-house PBMs taking over more and more of the market share between 2010 and 2018. He noted again that the market share for stand-alone PBMs is zero beginning in 2016 for various reasons, including their acquisition by insurers. Dr. Sood said his preliminary research examines how these changes in market share—the increase market share of in-house PBMs, the decrease in market share for rival PBMs, and the elimination of market share for stand-alone PBMs—are potentially affecting Medicare Part D beneficiaries, health care costs, and premiums. He discussed the concept of "customer foreclosure." He explained that because such a large share of the market, approximately 80% of the Medicare Part D market, is controlled by in-house PBMs, those customers served by these PBMs are not available to rival PBMs, which potentially reduces incentives and creates a barrier to market entry for new entrants, both PBM and insurer new entrants.

Dr. Sood next discussed the concept of "input foreclosure" and why it is relevant for understanding the impact of vertical integration. He explained that input foreclosure occurs when there is a lack of competition in the market, such as in-house PBMs holding a huge portion of the market share and lower market share for rival PBMs. This means that in-house PBMs have reduced incentives to provide high-quality PBM services at a competitive price to rival insurers—input foreclosure. He said input foreclosure could explain the increase in premium by insurers who obtain pharmacy services through a rival PBM from 2010–2018 versus in-house PBM premiums, which barely increased during the same period.

Dr. Van Nuys discussed potential policy solutions to the issues raised during the presentation: 1) enforce existing antitrust laws in key market segments; 2) encourage alternative PBM models, such as independent PBMs, to provide more market competition; 3) create full transparency within the distribution system; 4) pass prescription drug manufacturer rebates through to the patients at the point of sale; and 5) restrict PBMs to fixed fee rather than percent-of-price contracts.

Dr. Van Nuys responded to a question about what information in the reports used for the research related to insulin flow of money distribution chain was most helpful. She said that it would have been help if the Nevada report include more desegregated data and specifics related to insulin and/or specific diabetes drugs, which would also assist researchers in assessing the quality of the data. Mr. Meyer asked about the impact of pharmacy services administrative organizations (PSAOs) on the distribution system. Dr. Sood said it is unclear, but these entities could be trying to counteract the influence of such a small number of players in the prescription drug distribution system by giving pharmacies more bargaining power and leverage. He noted that it appears drug wholesalers are

acquiring more and more of the PSAOs also to get leverage over the PBMs. In addition, he noted that the drug wholesale market also is highly concentrated. He said that it seems that given the way the pharmaceutical distribution system is evolving, it is going to be just two or three large players along the prescription drug supply chain that are super vertically integrated and competing with other, which may not lead to the best outcomes for consumers

Mr. Rock asked about the firewalls that insurers and PBMs point to when countering questions about the impact of vertical integration on access and affordability of prescription drugs. Dr. Sood said one of the reasons he wanted to research vertical integration in the prescription drug market and pharmaceutical distribution system was to determine if such firewalls are effective. He said that based on his preliminary research, it does not appear they are effective. He said that if firewalls were effective, it would not matter if an insurer used a rival PBM for its pharmacy services, but his preliminary research shows it makes a difference in premium costs. The firewalls do not appear to be a significant enough of a barrier to reduce the incentives between the insurer and the PBM it owns when that PBM is working with a rival insurer. Dr. Van Nuys, noting that the preliminary research did not study firewalls, said some insurers with in-house PBMs assert vertical integration creates efficiencies. She said that if this is true, then net expenditures should be shrinking, but that does not appear to be happening. Mr. Eamon asked if Ms. Van Nuys looked at state laws with copayment caps on insulin. She said no but explained that a cap on out-of-pocket costs helps consumers at the point of sale, but such a cap does not reduce net expenditures. Consumers could still be paying more because of increased premium because the difference must be made up somewhere to cover the cost of the prescription drug because the total expenditure for that drug has remained the same.

Mr. Keen asked Dr. Sood and Dr. Van Nuys about the Federal Trade Commission's (FTC's) recently released request for information (RFI) related to PBM business practices. Dr. Van Nuys said she believes this is a good thing and that she is cautiously optimistic that the FTC could start enforcing its antitrust laws against certain PBM business practices. She said that she, Dr. Sood, and other researchers have been compiling information on these issues and plan to submit comments to the FTC in response to the RFI.

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

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Attachment Eight-D
Regulatory Framework (B) Task Force
8/10/22

Draft: 5/5/22

Pharmacy Benefit Manager Regulatory Issues (B) Subgroup
Kansas City, Missouri
April 4, 2022

The Pharmacy Benefit Manager Regulatory Issues (B) Subgroup of the Regulatory Framework (B) Task Force met in Kansas City, MO, April 4, 2022. The following Subgroup members participated: TK Keen, Chair, Numi Griffith and Ralph Margrish (OR); Laura Arp, Vice Chair (NE); Yada Horace (AL); Alan McClain and Beth Barrington (AR); Paul Lombardo (CT); Howard Liebers (DC); Andria Seip (IA); Vicki Schmidt and Julie Holmes (KS); Sharon P. Clark and Daniel McIlwain (KY); Chad Arnold (MI); Cynthia Amann (MO); David Dachs (MT); Ted Hamby and Robert Croom (NC); Renee Blechner (NM); Erin Porter (NJ); Glen Mulready and Kelli Price (OK); Ana Paulina Gomez (PA); Carlos Valles (PR); Scott McAnally (TN); Tanji J. Northrup (UT); Stephen Hogge and Katie Johnson (VA); Ned Gaines and Jennifer Kreitler (WA); Nathan Houdek and Jennifer Stegall (WI); Erin K. Hunter (WV); and Bryce Hamilton (WY).

1. Heard an Update from Oklahoma on Implementation of its PBM Law

Ms. Price discussed Oklahoma's Patient's Right to Pharmacy Choice Act, which was effective Nov. 1, 2019. The Act establishes a regulatory structure for pharmacy benefit managers (PBMs), including licensing requirements. She explained how the *Rutledge v. Pharmaceutical Care Management Association* case and the U.S. Supreme Court's decision in that case affected the Oklahoma Department of Insurance's (DOI's) implementation and enforcement of the Act and its potential effect on the U.S. District Court's ruling in the *Pharmaceutical Care Management Association v. Mulready* case.

Ms. Price said since Sept. 1, 2020, the Oklahoma DOI has received and reviewed almost 177,000 alleged violations of the Act. She said approximately 87,000 have been resolved to date. She said enforcement actions taken against PBMs include: eight cease-and-desist orders, 13 other orders, and five settlement agreements entered. Ms. Price described the specific issues the Oklahoma DOI is seeing, such as determining whether: 1) a regulation is a "cost regulation" or "central to plan administration regulation"; 2) settlement agreements made outside of the formal administrative process are confidential or are they subject to federal Freedom of Information Act (FOIA) and/or open records requests; and 3) for purposes of licensing, should a PBM and its financial status be reviewed for stability and solvency.

2. Heard a Presentation on PBM Regulation in Oregon

Mr. Griffith discussed Oregon's current PBM laws and regulations. He highlighted a few of the law and regulation provisions, including: 1) a PBM registration requirement; 2) maximum allowable cost (MAC) appeals process requirements; 3) a prohibition on requiring patients to use mail-order pharmacy; and 4) prohibiting "claw back" claims except under certain circumstances, such as fraudulent submission or duplicate claims. He said that currently 55 PBMs have registered with Oregon. Mr. Griffith explained that the Oregon DOI's enforcement of its PBM laws is driven by pharmacy complaints. He said that to date, the Oregon DOI has not initiated any enforcement actions because as far as the Oregon DOI knows, there have been no pharmacy complaints. He said this reflects PBMs satisfactory compliance with the law. He also highlighted that the Oregon DOI's regulations do not apply to health carriers that directly administer their pharmacy benefits, which is a limitation on the Oregon DOI's ability to review certain types of complaints related to its PBM law.

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Mr. Griffith next discussed Oregon's work related to prescription drug price transparency, including the work of the Joint Task Force for Fair Pricing of Prescription Drugs and its recommendations. He also noted that the Oregon Secretary of State Audits Division recently began an audit of all PBM contracts used by Medicaid managed care entities in Oregon.

Mr. Margrish, chair of the Oregon Prescription Drug Affordability Board (PDAB), discussed additional work being done in Oregon related to PBM transparency and the anticipated work of the PDAB related to PBM transparency. He said Oregon's PDAB legislation passed in 2021, which directs the PDAB to conduct affordability reviews for the health care system for high out-of-pocket costs for residents. He explained that the PDAB will meet for the first time this summer to develop its annual work plan, which will include identifying PBM transparency issues. He said that in addition to conducting affordability reviews, the PDAB is also tasked with studying the entire prescription drug distribution and payment system in Oregon and the policies adopted by other states and countries designed to lower the list price of prescription drugs.

With respect to the drug affordability reviews, Mr. Margrish explained that in conducting the reviews, the PDAB must look at multiple factors in the purchasing and supply chain, including: 1) the estimated total amount of the price concession, discount, or rebate the manufacturer provides to each PBM registered in Oregon for the prescription drug under review, expressed as a percentage of the prices; and 2) the estimated average price concession, discount, or rebate the manufacturer provides or is expected to provide to health insurance plans and PBMs in Oregon for therapeutic alternatives. He discussed Oregon's objectives with respect to transparency and cost, such as 1) identifying where the profits are distributed and living between industry and PBMs; 2) identifying its impact on the system and consumers; and 3) informing what drugs get presented to the PDAB for affordability reviews. He said the PDAB plans to implement through administrative rulemaking the criteria it must use to conduct the affordability reviews, which will take about four to six months. He said that means the PDAB will probably not begin conducting such reviews until the beginning of calendar year 2023. He said he would be happy to share the PDAB's findings to the Subgroup sometime next year.

Mr. Margrish discussed the analytic opportunities the PDAB's work will provide to inform policy because it will be examining the whole transaction and prescription drug distribution supply chain from end to end.

3. Heard a Presentation on the Subgroup's Charge to Develop a White Paper from a Consumer Perspective

Carl Schmid (HIV + Hepatitis Policy Institute) and Anna Schwamlein Howard (American Cancer Society, Cancer Action Network—ACS CAN) provided a consumer perspective on the Subgroup's charge to develop a white paper on PBMs and PBM business practices.

Mr. Schmid discussed the role of PBMs in prescription drug access and affordability for consumers. He discussed how PBMs are involved in formulary decisions and potential factors influencing these decisions, including which drugs will be covered, adding newly approved drugs, removal of drugs, and drug exclusions. He also discussed how PBMs affect prescription drug affordability particularly due to increased prescription drug cost-sharing and other factors affecting health care costs for consumers.

Mr. Schmid also touched on the importance of prescription copayment assistance to consumers and its role in helping to reduce out-of-pocket costs. With respect to such assistance, he discussed copayment accumulator adjustment programs, which are programs that restrict a prescription drug manufacturer's assistance coupon from counting towards a patient's deductible or other out-of-pocket cost-sharing requirement. He also discussed: 1) the percentage of plans in states with copayment accumulator policies and states with laws banning copayment

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accumulators; 2) potential conflicts of state copayment accumulator ban laws with federal requirements related to health savings account (HSA)-qualified high deductible health plan (HDHP) and continued eligibility to contribute to an HSA in light of such a law; and 3) potential solutions to address the issue.

Ms. Howard said the Subgroup's proposed [State] Pharmacy Benefit Manager Licensure and Regulation Act was an important first step. She said the NAIC consumer representatives strongly support the development of the white paper. She said the white paper is an opportunity for the Subgroup to build on the policies included in the proposed model's Section 8—Regulations drafting note and when finished, it will offer a road map for states that might want to go further than what was included in the draft model. She suggested the Subgroup consider additional topics not included in the drafting note related to provisions in PBM laws that states have enacted, such as PBM network adequacy requirements, prior authorization requirements, and PBM complaint process requirements. She discussed additional items the Subgroup should consider for inclusion in the white paper, including: 1) clearly defining health carrier obligations; 2) sharing rebates with patients; and 3) the impact of the *Rutledge* decision and other PBM-related cases working their way through the courts.

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

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