

Date: 7/21/21

*Virtual Meeting*

**REGULATORY FRAMEWORK (B) TASK FORCE**

Wednesday, July 28, 2021

11:00 a.m.– 12:00 p.m. ET / 10:00 – 11:00 a.m. CT / 9:00 – 10:00 a.m. MT / 8:00 – 9:00 a.m. PT

**ROLL CALL**

Michael Conway, Chair	Colorado	Anita G. Fox	Michigan
Glen Mulready, Vice Chair	Oklahoma	Grace Arnold	Minnesota
Jim L. Ridling	Alabama	Chlora Lindley-Myers	Missouri
Lori K. Wing-Heier	Alaska	Eric Dunning	Nebraska
Peni Itula Sapini Teo	American Samoa	Chris Nicolopoulos	New Hampshire
Evan G. Daniels	Arizona	Marlene Caride	New Jersey
Ricardo Lara	California	Mike Causey	North Carolina
Andrew M. Mais	Connecticut	Jon Godfread	North Dakota
Karima M. Woods	District of Columbia	Judith L. French	Ohio
David Altmaier	Florida	Andrew R. Stolfi	Oregon
Dean L. Cameron	Idaho	Jessica K. Altman	Pennsylvania
Dana Popish Severinghaus	Illinois	Larry D. Deiter	South Dakota
Amy L. Beard	Indiana	Doug Slape	Texas
Doug Ommen	Iowa	Jonathan T. Pike	Utah
Vicki Schmidt	Kansas	Scott A. White	Virginia
Sharon P. Clark	Kentucky	Mike Kreidler	Washington
Eric A. Cioppa	Maine	James A. Dodrill	West Virginia
Gary D. Anderson	Massachusetts	Mark Afable	Wisconsin
Staff Support: Jolie Matthews/Jennifer Cook			

**AGENDA**

1. Consider Adoption of its June 15 and March 25, 2021, Minutes  
—*Commissioner Michael Conway (CO)*
2. Consider Adoption of its Subgroup and Working Group Reports
  - a. Accident and Sickness Insurance Minimum Standards (B) Subgroup  
—*Laura Arp (NE) and Andrew Schallhorn (OK)*
  - b. Employee Retirement Income Security Act (ERISA) (B) Working Group—*Robert Wake (ME)*
  - c. Mental Health Parity and Addiction Equity Act (MHPAEA) (B) Working Group—*Katie Dzurec (PA)*
  - d. Pharmacy Benefit Manager Regulatory Issues (B) Subgroup—*TK Keen (OR)*
3. Hear a Work Status Update:
  - a. ERISA (B) Working Group—*Jolie Matthews (NAIC)*
  - b. Pharmacy Benefit Manager Regulatory Issues (B) Subgroup—*TK Keen (OR)*

4. Hear an Update on the Center on Health Insurance Reforms' (CHIR's) Work Related to the Federal Affordable Care Act (ACA)—*Christine Monahan (CHIR, Georgetown University's McCourt School of Public Policy)*
5. Hear a Presentation on the Federal No Surprises Act (NSA) Interim Final Rules—*Katie Keith (Out2Enroll) and Jack Hoadley (Georgetown University Health Policy Institute)*
6. Discuss Any Other Matters Brought Before the Task Force—*Commissioner Michael Conway (CO)*
7. Adjournment

**Agenda Item #1**

**Consider Adoption of its June 15 and March 25, 2021, Minutes**  
**—Commissioner Michael Conway (CO)**

Draft: 7/8/21

Regulatory Framework (B) Task Force  
Virtual Meeting  
June 15, 2021

The Regulatory Framework (B) Task Force met June 15, 2021. The following Task Force members participated: Michael Conway, Chair (CO); Glen Mulready, Vice Chair, represented by Andrew Schallhorn and Mike Rhoads (OK); Lori K. Wing-Heier represented by Sarah Bailey (AK); Jim L. Ridling represented by William Rodgers, Reyn Norman, and Yada Horace (AL); Evan G. Daniels represented by Jon Savary (AZ); Ricardo Lara represented by Bruce Hinze and Tyler McKinney (CA); Andrew N. Mais represented by Jared Kosky (CT); David Altmaier represented by Chris Struk (FL); Doug Ommen (IA); Dean L. Cameron represented by Kathy McGill (ID); Dana Popish Severinghaus represented by Eric Anderson and Ryan Gillespie (IL); Amy L. Beard represented by Claire Szpara and Alex Peck (IN); Vicki Schmidt (KS); Sharon P. Clark (KY); Gary D. Anderson represented by Kevin Beagan (MA); Eric A. Cioppa represented by Robert Wake (ME); Anita G. Fox represented by Chad Arnold, Sarah Wohlford, and Karen Dennis (MI); Grace Arnold represented by Galen Benshoof, Chad Arnold, and Sherri Mortensen-Brown (MN); Chlora Lindley-Myers represented by Amy Hoyt and Camille Anderson-Weddle (MO); Mike Causey represented by Robert Croom (NC); Jon Godfread represented by Chrystal Bartuska (ND); Eric Dunning represented by Martin Swanson and Tom Green (NE); Chris Nicolopoulos represented by Maureen Belanger (NH); Marlene Caride represented by Chanell McDevitt (NJ); Judith L. French represented by Marjorie Ellis (OH); Andrew R. Stolfi represented by TK Keen (OR); Jessica K. Altman (PA); Larry D. Deiter represented by Jill Kruger (SD); Doug Slape represented by Rachel Bowden and David Bolduc (TX); Jonathan T. Pike represented by Tanji J. Northrup (UT); Scott A. White represented by Don Beatty (VA); Mike Kreidler represented by Molly Nollette (WA); Mark Afable represented by Nathan Houdek and Jennifer Stegall (WI); and James A. Dodrill represented by Ellen Potter (WV).

1. Adopted a New Pharmacy Benefit Manager Regulatory Issues (B) Subgroup Proposed Charge

Commissioner Conway said that during the Task Force's March 18 meeting, the Task Force discussed and agreed to consider a new 2021 charge for the Pharmacy Benefit Manager Regulatory Issues (B) Subgroup to develop a white paper consistent with some of the comments received on the draft [State] Pharmacy Benefit Manager Licensure and Regulation Model Act (PBM model). He said that prior to the meeting, NAIC staff distributed a draft of the proposed charge for the Subgroup to "develop a white paper to: 1) analyze and assess the role PBMs 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."

Commissioner Conway said the Task Force received comments on the proposed charge from America's Health Insurance Plans (AHIP), the Blue Cross and Blue Shield Association (BCBSA), the National Community Pharmacists Association (NCPA), and the Pharmaceutical Care Management Association (PCMA). He requested comments from the Task Force on the proposed charge. Mr. Swanson expressed support for the proposed charge, particularly the importance of cataloging current state laws regulating pharmacy benefit manager (PBM) business practices and emerging state laws. He also stressed the importance of examining PBM functions and seeing how they are operating. Mr. Swanson also discussed the importance of the white paper including some sort of analysis of the cost versus the benefits of PBM regulation and how it is working operationally with respect to consumers and other stakeholders, such as state departments of insurance (DOIs). He said it is important that the white paper examine the entire prescription drug supply chain, starting with the prescription drug manufacturers to the insurer contracts with the PBMs, pharmacists, and other entities involved in the supply chain, and ending with the end user, the consumer. The white paper should not just focus on PBMs. Mr. Swanson also agreed that it is important the white paper examine the *Rutledge* decision and the implications of that decision, if any, on states implementing laws on PBM business practices, including contracting issues.

Mr. Wake expressed support for Mr. Swanson's comments suggesting the white paper examine the entire prescription drug supply chain. He also agreed with Mr. Swanson's comments concerning the *Rutledge* decision. Mr. Kosky also agreed with Mr. Swanson's comments with respect to examining and understanding the entire prescription drug supply chain to avoid the balloon effect of making regulatory changes to one part of the supply chain, which might affect costs and unintentionally shifting that change in cost to another part of the chain. Additional Task Force members expressed support for broadening the proposed charge to include other entities in the prescription drug supply chain. The Task Force also discussed, but it deferred

deciding on, whether the Pharmacy Benefit Manager Regulatory Issues (B) Subgroup's name would have to be changed to reflect the addition of other entities involved in the prescription drug supply chain.

Kris Hathaway (AHIP) discussed AHIP's comment letter. She explained AHIP's recommendation to broaden the proposed charge to include other entities in the prescription drug supply chain in addition to PBMs and the role these entities play in the provision of affordable prescription drug benefits. She noted the recent passage of pharmacy service administrative organization (PSAO) transparency legislation in Maryland. She said this legislation illustrates steps the states can take to conduct a more thorough, holistic review of the prescription drug supply chain and better understand all aspects of drug pricing. Ms. Hathaway also said AHIP supports the NAIC conducting an analysis of the *Rutledge* decision. Randi Chapman (BCBSA) said the BCBSA, like AHIP, supports broadening the proposed charge to include other entities in the prescription drug supply chain. She said the BCBSA also supports the NAIC's planned analysis of the *Rutledge* decision. She noted that this year, at least 35 states have introduced PBM legislation in response to that decision. Given this, it is important for the NAIC to review and analyze this legislation to fully understand the scope of these bills and any unintentional barriers such legislation could place on patient access to medication.

Lauren Rowley (PCMA) discussed the PCMA's comment letter, which includes a recommendation to expand the charge to include other entities involved in the prescription drug supply chain. She also noted the recent legislation passed in Maryland related to PSAOs and similar legislation recently passed in Louisiana. Ms. Rowley said that although it is not included in the PCMA's written comments, the PCMA reiterates its suggestion that the Employee Retirement Insurance Security Act (ERISA) (B) Working Group is the more appropriate NAIC group to initially examine the *Rutledge* decision given its members' expertise on ERISA preemption issues.

The Task Force discussed the PCMA's suggested revisions to the proposed charge. Some Task Force members expressed concern with potentially narrowing the charge with the PCMA's suggestion to revise the language to state "PBM business practices *related to drug prices*," particularly if one goal of this proposed charge is to allow the Pharmacy Benefit Manager Regulatory Issues (B) Subgroup to examine the business practices in the drafting note in Section 8—Regulations of the draft [State] Pharmacy Benefit Manager Licensure and Regulation Model Act. For similar reasons, some Task Force members expressed concern with deleting the word "rebating" and substituting in its place the language "manufacturer rebates." Ms. Rowley explained the PCMA's reasoning for narrowing the proposed charge with its suggested revisions.

Matthew Magner (NCPA) discussed the NCPA's comments, including its suggested revisions to the proposed charge. He said the NCPA suggests certain revisions to the proposed charge in recognition of the fact that PBMs play a larger role in the provision of prescription drug benefits far beyond administering reimbursements to providers on behalf of insurers, such as creating provider networks, negotiating drug prices and rebates, and developing drug formularies. Mr. Magner said the NCPA also believes it is important the proposed charge includes not only identifying, examining, and describing current and emerging state regulatory approaches to PBM business practices, but their sources of revenue as well. He said another suggested revision to the proposed charge would require a discussion of any challenges the states have in investigating violations of their laws or regulations. The Task Force discussed NCPA's suggested revisions to the proposed charge. After discussion, the Task Force concluded that generally, the language of the proposed charge would address the NCPA's suggested revisions.

Carl Schmid (HIV+Hepatitis Policy Institute) expressed support for the proposed charge, noting the NAIC consumer representatives had initially suggested the Subgroup be charged with developing a white paper during the Task Force's March 18 meeting. He said the NAIC consumer representatives did have questions as to the process the Subgroup would use to complete the proposed charge, such as contracting out to a third party, and the timeline for completing the charge. He also noted the role PBMs play in other aspects of the prescription drug supply chain, such as PBMs' role in determining patient cost. Mr. Schmid also expressed support for including the NCPA's suggested revisions to the proposed charge and expansion of the charge beyond a focus on drug pricing, as the PCMA suggests.

Commissioner Conway said that based on the discussion, he believes the Task Force has consensus to revise the proposed charge to add the following language from the PCMA's comment letter: "Pharmacy Services Administrative Organizations (PSAOs) and other supply chain entities." No one disagreed.

Mr. Hinze made a motion, seconded by Mr. Keen to add the PCMA language to the proposed charge (Attachment One-A). The motion passed unanimously.

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

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DRAFT

Regulatory Framework (B) Task Force  
Virtual Meeting *(in lieu of meeting at the 2021 Spring National Meeting)*  
March 25, 2021

The Regulatory Framework (B) Task Force met March 25, 2021. The following Task Force members participated: Michael Conway, Chair (CO); Bruce R. Ramage, Vice Chair (NE); Lori K. Wing-Heier (AK); Jim L. Ridling represented by Jennifer Li and Yada Horace (AL); Peni Itula Sapini Teo represented by Elizabeth Perri (AS); Evan G. Daniels represented by Sterling Gavette (AZ); Ricardo Lara represented by Bruce Hinze (CA); Andrew N. Mais represented by Jared Kosky (CT); Karima M. Woods represented Howard Liebers (DC); David Altmaier represented by Chris Struk (FL); Doug Ommen represented by Andria Seip (IA); Dean L. Cameron (ID); Dana Popish Severinghaus represented by Shannon Whalen and Eric Anderson (IL); Stephen W. Robertson represented by Claire Szpara (IN); Vicki Schmidt represented by Tate Flott, Julie Holmes, Chris Hollenbeck and Shannon Lloyd (KS); Sharon P. Clark (KY); Gary D. Anderson represented by Rebecca Butler (MA); Eric A. Cioppa represented by Robert Wake (ME); Anita G. Fox represented by Sarah Wohlford and Karen Dennis (MI); Grace Arnold represented by Peter Brickwedde (MN); Chlora Lindley-Myers represented by Amy Hoyt and Camille Anderson-Weddle (MO); Mike Causey represented by Robert Croom (NC); Jon Godfread (ND); Chris Nicolopoulos represented by Michelle Heaton (NH); Marlene Caride represented by Chanell McDevitt (NJ); Judith L. French (OH); Glen Mulready (OK); Andrew R. Stolfi (OR); Jessica K. Altman (PA); Larry D. Deiter (SD); Doug Slape represented by Rachel Bowden, Richard Lunsford and Doug Danzeiser (TX); Jonathan T. Pike represented by Tanji J. Northrup and Jaakob Sundberg (UT); Scott A. White represented by Don Beatty (VA); Mike Kreidler represented by Molly Nollette (WA); Mark Afable represented by Nathan Houdek and Jennifer Stegall (WI); and James A. Dodrill (WV).

1. Adopted its March 18, 2021; March 1, 2021; and 2020 Fall National Meeting Minutes

The Task Force met March 18, 2021; March 1, 2021; and Nov. 19, 2020. During these meetings, the Task Force discussed comments received on the draft the [State] Pharmacy Benefit Manager Licensure and Regulation Model Act (PBM Model Act) and adopted the PBM Model Act.

Ms. Nollette made a motion, seconded by Commissioner Deiter, to adopt the Task Force's March 18, 2021 (Attachment One), March 1, 2021 (Attachment Two); and Nov. 19, 2020 (*see NAIC Proceedings – Fall 2020, Regulatory Framework (B) Task Force*) minutes. The motion passed unanimously.

2. Adopted its Subgroup and Working Group Reports

Ms. Nollette made a motion, seconded by Commissioner Deiter, to adopt the following reports: the Accident and Sickness Insurance Minimum Standards (B) Subgroup; the Employee Retirement Income Security Act (ERISA) (B) Working Group; the Mental Health Parity and Addiction Equity Act (MHPAEA) (B) Working Group, including its Jan. 28 minutes (Attachment Three); and the Pharmacy Benefit Manager Regulatory Issues (B) Subgroup. The motion passed unanimously.

3. Heard an Update on the CHIR's Work Related to the ACA

Justin Giovannelli (Center on Health Insurance Reforms—CHIR, Georgetown University Health Policy Institute) provided an update on the CHIR's work related to the federal Affordable Care Act (ACA) and recently enacted federal laws such as the federal No Surprises Act (NSA) and the federal American Rescue Plan Act (ARPA) and other issues of interest to state insurance regulators. He discussed the CHIR's efforts to assess the impact of the extended special enrollment periods (SEPs) into the federal health insurance exchanges, as provided in the ARPA, on access and affordability of coverage and how it will be implemented. The CHIR is particularly interested in assessing the impact of these provisions on the individual market given that some are temporary. He also discussed the CHIR's work related to the federal and state implementation of the NSA.

Mr. Giovannelli said the CHIR is also looking at the issue of the "family glitch" and potential solutions. The "family glitch" is the ACA rule that bases eligibility for a family's premium subsidies on whether available employer-sponsored insurance is affordable for the employee only, even if it is not actually affordable for the whole family. The CHIR is continuing its work to track state regulatory reforms affecting the individual market, such as the ACA's Section 1332 waiver program, including whether the states are looking at other options, in addition to reinsurance programs, considering the ARPA and other Biden administration changes, that could positively affect the affordability of comprehensive coverage. The CHIR anticipates publishing an issue brief on this topic soon.

Mr. Giovannelli also discussed some of the CHIR's upcoming work on network adequacy and standardized health plans and noncomprehensive coverage arrangements. He said the CHIR is continuing its work of tracking state regulatory approaches to the COVID-19 pandemic. Additionally, Mr. Giovannelli highlighted the CHIR's ongoing state technical assistance regarding insurance regulatory matters with the support of the Robert Wood Johnson Foundation (RWJF) through its State Health and Value Strategies Program and the support of the Laura and John Arnold Foundation (LJAF).

Commissioner Conway asked Mr. Giovannelli if the CHIR, as part of its work it plans to do with respect to noncomprehensive plans and health care sharing ministries, would be examining its appeal to consumers considering the ARPA and its new provisions enhancing the affordability of comprehensive coverage in the individual market. Mr. Giovannelli said the CHIR would be looking at this as part of its study.

#### 4. Heard a Presentation on the NSA

Jack Hoadley (Georgetown University Health Policy Institute) presented on the NSA. He discussed the NSA's scope, including what types of plans it covers and where its protections apply. The NSA does not apply to short-term plans and excepted benefits plans. It also does not apply to ground ambulance services, but it does apply to air ambulance services. Mr. Hoadley also described how the NSA protects patients from balance bills by requiring that patients be held responsible for in-network cost sharing only and barring providers from sending or collecting a bill for amounts other than in-network cost sharing.

Mr. Hoadley also discussed a key component of the NSA—determining the payment amount for out-of-network care when there is a payment dispute. He discussed how the payment amount would be determined: 1) for states with a “specified state law” that includes a method for determining the payment, the state method applies for the health plans regulated by the state and for the services to which the state law applies; and 2) for other states or for plans not regulated by the state (self-funded plans), the federal method applies. The state method is likely to apply in the 18 states with comprehensive surprise billing laws and in several states with partial protections for applicable services.

Mr. Hoadley explained that with respect to air ambulance services, consumers are protected from balance billing similar to the NSA's consumer protections for emergency services. The federal independent dispute resolution (IDR) system would apply. The NSA includes no protections for ground ambulance services, but it does include a provision establishing an Advisory Committee on Ground Ambulances and Patient Billing (Advisory Committee) that will make recommendations for the states and the U.S. Congress on addressing balance billing issues for such services.

Mr. Hoadley described the NSA's enforcement mechanisms and the role that the states will have in enforcement. The state departments of insurance (DOIs) are the primary enforcers of provisions that apply to insurers and fully insured group health plans. The federal government is the enforcer in the states that fail to substantially enforce the law and for self-funded group health plans. He discussed how the NSA's provisions will be enforced on health care providers. He explained that the states may enforce provisions on providers, including air ambulances, but the federal government will do so where a state fails to substantially enforce the law. He noted that unless addressed through federal rule-making, the NSA is silent on which state agency is responsible for enforcing provider provisions. Given that state DOIs typically do not have jurisdiction over providers, the states that have current balance billing laws have taken various approaches regarding provider enforcement, such as vesting that authority in the state DOI, health department, medical licensing entity or the state attorney general's office. Other states have taken a blended approach by allowing the state DOI or provider licensing entity to report patterns of unresolved or intentional violations to another entity for enforcement. Mr. Hoadley also discussed how, in some cases, determining the primary enforcer—federal or state—could be challenging, which is why the states need to begin communicating with the federal agencies charged with implementing the NSA to try to address and avoid these situations.

Mr. Hoadley discussed what questions remain with the NSA with respect to states that currently have balance billing laws and those that do not. He also identified specific opportunities and questions for the states to engage with the federal agencies implementing the NSA to obtain clarification on outstanding issues prior to federal rulemaking. Additionally, he discussed next steps regarding the NSA, including the timeline for anticipated federal regulations.

Commissioner Conway asked Mr. Hoadley if he had any thoughts on why the NSA does not address ground ambulance services. Commissioner Conway said Colorado does have provisions concerning ground ambulance services, but it was a struggle for Colorado to find the right balance in crafting its provisions. Mr. Hoadley said Colorado's experience in trying to address the ground ambulance services issues is reflective of possibly why the U.S. Congress could not reach agreement on provisions to include in the NSA on ground ambulance services. He said another issue is that ground ambulance services typically involve local county and city governments, which adds to the complexity of the issue. As such, the U.S. Congress punted the issue to the Advisory Committee.

Commissioner Conway asked about the NSA's enforcement provisions related to health care providers. Mr. Hoadley explained that the NSA makes the states the primary enforcers regarding providers with a federal backstop if a state fails to substantially enforce the NSA's provisions on providers. He said states that currently have balance billing laws have discovered the importance of educating providers on the front end about their laws' provisions rather than waiting for a violation. He said the Health Policy Institute has been talking to the states to learn more about their experiences on this issue and hopes to learn more.

##### 5. Heard a Discussion of the Decision in *Rutledge v. PCMA*

Katie Keith (Out2Enroll) discussed the recent U.S. Supreme Court's decision in *Rutledge v. the Pharmaceutical Care Management Association* (PCMA) and its potential effect on the ability of state insurance regulators to regulate certain pharmacy benefit manager (PBM) business practices. Among the roles PBMs play in the provision of prescription drugs, PBMs act as intermediaries between pharmacies and prescription drug plans. In that role, PBMs reimburse pharmacies for the cost of drugs covered by prescription drug plans. To determine the reimbursement rate for each drug, PBMs develop and administer maximum allowable cost (MAC) lists.

Ms. Keith said that in 2015, Arkansas passed Act 900. The Arkansas law effectively requires PBMs to reimburse Arkansas pharmacies at a price equal to or higher than the pharmacy's wholesale cost. To accomplish this result, Act 900: 1) requires PBMs to timely update their MAC lists when drug wholesale prices increase; 2) provides pharmacies an administrative appeal procedure to challenge MAC reimbursement rates; and 3) allows pharmacies to decline to sell a prescription drug if PBM reimbursement is below acquisition costs. The PCMA sued in the Eastern District of Arkansas, arguing that Act 900 is preempted under ERISA. Following a precedent set in a case, *Pharmaceutical Care Mgmt. Assn. v. Gerhart*, 852 F. 3d 722 (2017), involving a similar Iowa statute, the District Court held that ERISA preempts Act 900, and the U.S. Court of Appeals for the Eight Circuit affirmed that decision. Ms. Keith said the U.S. Supreme Court granted writ of certiorari in the case, held oral arguments Oct. 6, 2020, and issued its decision Dec. 10, 2020. She said that in a unanimous decision written by Associate Justice Sonia Sotomayor and concurrence by Associate Justice Clarence Thomas, the Court held that Act 900 is not preempted by ERISA. Ms. Keith said this decision most likely opens up a whole range of options for those states considering PBM regulation.

Ms. Keith explained the Court's analysis. She also summarized some of the standards from previous Court decisions related to ERISA preemption and how the Court in this case most likely weighed whether Act 900 was more like the *New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645 (1995) case, which the Court found concerned rate regulation that only affects the costs of ERISA plans, or the *Gobeille v. Liberty Mutual Insurance Company*, 136 S. Ct. 936 (2016) case.

Ms. Keith said the Court found Act 900 is more like the *Travelers* case. Act 900 is "merely a form of cost regulation" by requiring PBMs to reimburse pharmacies at a certain level that does not bear an impermissible connection with or reference to ERISA. The Court reasoned that "ERISA does not preempt state rate regulations that merely increase costs or alter incentives for ERISA plans without forcing plans to adopt any particular scheme of substantive coverage." Act 900:1) does not "refer to" ERISA; 2) does not apply "immediately and exclusively" to ERISA plans; and 3) its application to ERISA plans is not "essential to the law's operation." Ms. Keith said the Court also held that Act 900 does not directly regulate health plans at all and applies to PBMs whether they act pursuant to an ERISA plan or not.

Ms. Keith said the Court rejected the PCMA's argument that Act 900's enforcement mechanisms directly affect central matters of plan administration and interfere with nationally uniform plan administration. The Court said Act 900's enforcement mechanisms do not require plan administrators to structure their benefit plans in a particular way: 1) Act 900 "simply establishes a floor for the cost of benefits that plans choose to provide;" 2) ERISA does not preempt state laws that merely increase costs even if plans decide to limit benefits or charge higher rates as a result; and 3) PCMA's position would preempt any state laws that could affect the price or provision of benefits.

Ms. Keith reiterated that she believes the *Rutledge* decision has big implications for the states with respect to PBM regulation, particularly on cost containment and the direct regulation of health care costs. She noted, however, that states are still not going to be able to regulate ERISA plans, but to the extent states are looking at hospitals and other actors in the health care system, the *Rutledge* case provides opportunities. She also said she anticipates more litigation related to these issues. Commissioner Conway said he anticipates more discussion of the *Rutledge* case as part of the Pharmacy Benefit Manager Regulatory Issues (B) Subgroup's future work to develop a white paper on state options with respect to regulating PBM business practices and the ERISA (B) Working Group's discussion of the case's potential impact with respect to ERISA preemption.

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

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**Agenda Item #2**

**Consider Adoption of its Subgroup and Working Group Reports**  
**—*Commissioner Michael Conway (CO)***

*Virtual Meetings*

**ACCIDENT AND SICKNESS INSURANCE MINIMUM STANDARDS (B) SUBGROUP**

**July 26, 2021 / July 12, 2021 / June 7, 2021**

**Summary Report**

The Accident and Sickness Insurance Minimum Standards (B) Subgroup of the Regulatory Framework (B) Task Force met July 26, July 12 and June 7, 2021. During these meetings, the Subgroup:

1. Established a new public comment period ending July 2 to receive comments on Sections 1-7 of the *Model Regulation to Implement the Accident and Sickness Insurance Minimum Standards Model Act* (#171).
2. Begin its discussion of the comments received on Sections 1-7 of Model #171 received by the July 2 public comment deadline. The Subgroup anticipates meeting approximately every two weeks to continue its discussions of the comments received.

Draft: 7/23/21

Accident and Sickness Insurance Minimum Standards (B) Subgroup  
Virtual Meeting  
July 12, 2021

The Accident and Sickness Insurance Minimum Standards (B) Subgroup of the Regulatory Framework (B) Task Force met July 12, 2021. The following Subgroup members participated: Laura Arp, Co-Chair (NE); Andrew Schallhorn, Co-Chair (OK); Debra Judy (CO); Chris Struk and Shannon Doheny (FL); Robert Wake (ME); Sherri Mortensen-Brown (MN); Camille Anderson-Weddle (MO); Gayle Woods (OR); Kathleen Kellock (SC); Rachel Bowden (TX); Tanji J. Northrup (UT); Ned Gaines (WA); and Jennifer Stegall (WI).

1. Discussed Revisions to Model #171

Ms. Arp said during the Subgroup's June 7 meeting, the Subgroup requested new comments and additional comments on Sections 1 through 7 of the *Model Regulation to Implement the Accident and Sickness Insurance Minimum Standards Model Act* (#171). She said she would like the Subgroup to review and discuss those comments beginning with Section 1—Purpose using the comment chart NAIC staff prepared. There was no objection.

The Subgroup discussed the Missouri Department of Insurance's (DOI's) suggestion to add the word "renewal" to Section 1. The Subgroup agreed to add the word "renewal." No comments were received on Section 2—Authority.

The Subgroup next discussed the Blue Cross Blue Shield Association's (BCBSA's) suggestion to add language to Section 3A—Application and Scope defining the term "short-term, limited-duration insurance" to ensure that there is consistency with the meaning and use of this term in both the *Supplementary and Short-Term Health Insurance Minimum Standards Model Act* (#170) and this model, which is Model #170's companion model regulation. The Subgroup discussed the BCBSA's suggested revision. The Subgroup also discussed whether it should consider adding a new section to Model #171 for definitions that apply to the model along with Section 5—Policy Definitions, which defines terms used in a policy. After additional discussion, the Subgroup agreed to potentially add the BCBSA's suggested revision and add a new section defining terms used in Model #171, such as a definition of "short-term, limited-duration insurance" and any other terms used only in Model #171. The Subgroup also agreed to specifically discuss what terms should be included in the new definition section after it finishes its review and discussion of suggested revisions to Model #171. The Subgroup also discussed the need for it to be aware that short-term, limited-duration (STLD) insurance, which is a form of major medical insurance, will need to be treated differently than the other types of policies covered in Model #171, which are supplemental policies.

The Subgroup agreed to accept the Missouri DOI's suggestion to delete "shall apply" and substitute "applies" in Section 3B.

The Subgroup also agreed to accept the Health Benefits Institute's (HBI's) suggested revision to Section 3C to add language that Model #171 does not apply to limited long-term care insurance (LTCI) policies subject to the requirements of the *Limited Long-Term Care Insurance Model Act* (#642).

No comments were received on Section 4—Effective Date.

The Subgroup next discussed Section 5, beginning with the BCBSA's suggested comments on Section 5A to revise the language to refer to "a supplementary policy or short-term, limited-duration insurance." Randi Chapman (BCBSA) said the BCBSA's suggestion is consistent with the discussion related to Section 3A. The Subgroup discussed whether it should add the word "certificate" to address group coverage. Mr. Wake suggested that the Subgroup needs to examine the changes made to Model #170 to ensure that the revisions, both substantively and related to terminology, to Model #171 are consistent with those changes. He said there are various approaches the Subgroup could use to encompass the similarities between supplementary coverage and STLD insurance coverage and figure out what provisions should or should not apply to STLD policies.

Ms. Arp suggested that the Subgroup consider revising the language to state, "short-term, limited-duration coverage" for consistency with Model #170. Ms. Bowden said she does not have an objection to Ms. Arp's suggestion, but she said the Subgroup needs to keep in mind the idea of adding "certificate," as appropriate, when using the term "policy." She suggested that the Subgroup might want to consider adding a definition of "policy," which would include the term "certificate." The Subgroup discussed this issue and the issue of having two definition sections—one for definitions of terms used in Model #171

and the other for terms used in the policy, which is currently Section 5. Ms. Arp pointed out that Model #170 includes a definition of “policy.” She said if the Subgroup wants to find a term for “policy” that will also mean “certificate” or other similar terms, then it would have to find another term to use.

Chris Petersen (Arbor Strategies LLC) suggested that the issue the Subgroup is discussing might not be a definitional issue, but a scope and applicability issue that can be more appropriately addressed in Section 3. Mr. Wake said Mr. Petersen’s suggestion might not address potential issues with regulating a group master policy versus regulating an individual policy. He stressed that whatever approach the Subgroup decides to take that it be consistent. J.P. Wieske (HBI) said this issue illustrates how the Subgroup will have to carefully craft revisions differentiating between STLD insurance coverage and the other types of coverages regulated in Model #171. Mr. Petersen said this also illustrates why STLD insurance coverage should have its own section in Model #171. The Subgroup discussed the issue of group coverage and STLD insurance coverage. Mr. Wieske said the Subgroup might have to consider dealing with it by using terminology such as “individually underwritten policy.” Ms. Arp said as already discussed, the Subgroup will add another definition section to define terms used in Model #171; but to deal with this issue, the Subgroup might have to add in its section for STLD insurance coverage, a provision defining certain terms that would apply only to that type of coverage.

Mr. Schallhorn suggested that the Subgroup might have to use the language “policy or certificate” when referring to STLD insurance coverage. The Subgroup discussed Mr. Schallhorn’s suggestion. The Subgroup also discussed the implications of adding “certificate,” which could potentially require state DOIs to review each certificate. After additional discussion, the Subgroup decided not to make the revision.

The Subgroup discussed other suggestions to revise Section 5A, including revising it to state, “[e]xcept as provided in this regulation, all policies subject to this regulation shall use the definitions as provided in this section.” The Subgroup discussed an issue that not all policies subject to Model #171 would use all the policy definitions in Section 5. To address this issue, the Subgroup discussed whether to revise the suggested revision to Section 5A to state, “[e]xcept as provided in this regulation, to the extent these definitions are used in a policy or certificate, all policies subject to this regulation shall use the definitions as provided in this section.” The Subgroup discussed how to incorporate the idea that the definitions are a minimum standard, but also permit deviations when favorable to the consumer. Ms. Arp suggested that the Subgroup consider for discussion during its next meeting July 26 the language, “shall not be defined more restrictively” and “shall not be more restrictive.” She said this language is used in several of the policy definitions in Section 5, such as the definition of “preexisting condition,” “sickness,” and “total disability.” The Subgroup discussed this with respect to whether such language is favorable or unfavorable to the consumer. The Subgroup also discussed how this is further complicated in the policy definition of “preexisting condition” because of its inclusion of the prudent person standard language.

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

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Draft: 6/14/21

Accident and Sickness Insurance Minimum Standards (B) Subgroup  
Virtual Meeting  
June 7, 2021

The Accident and Sickness Insurance Minimum Standards (B) Subgroup of the Regulatory Framework (B) Task Force met June 7, 2021. The following Subgroup members participated: Laura Arp, Co-Chair (NE); Andy Schallhorn, Co-Chair (OK); Debra Judy (CO); Chris Struk (FL); Robert Wake (ME); Sherri Mortensen-Brown (MN); Camille Anderson-Weddle (MO); Katie Dzurec (PA); Shari Miles (SC); Rachel Bowden (TX); Heidi Clausen and Shelley Wiseman (UT); Kimberly Tocco (WA); and Nathan Houdek and Jennifer Stegall (WI).

1. Discussed the Model #171 Working Draft

Jolie H. Matthews (NAIC) walked the Subgroup through a working draft of preliminary revisions to the *Model Regulation to Implement the Accident and Sickness Insurance Minimum Standards Model Act (#171)* (Attachment ?-A). She explained that the preliminary revisions in italics reflect Subgroup decisions made during the Subgroup's meetings in late 2019. Ms. Matthews said other preliminary revisions reflect her attempt to revise Model #171 for consistency with the *Supplementary and Short-Term Health Insurance Minimum Standards Model Act (#170)*, which is the companion model to Model #171. She highlighted provisions the Subgroup had deferred deciding on whether to revise, including revisions to the term "preexisting condition" in Section 5L—Policy Definitions.

Ms. Matthews said that during the Subgroup's last meeting on Dec. 16, 2019, the Subgroup ended its discussion of the comments received on Sections 1–5 with the term "total disability" in Section 5O. She said that also during this meeting, the Subgroup set a public comment deadline ending Feb. 7, 2020, to receive comments on Sections 6–7 of Model #171. She said the comments received by the Feb. 7, 2020, public comment deadline are posted on the Subgroup's web page on the NAIC website.

Ms. Matthews explained that during its Dec. 16, 2019, meeting, the Subgroup requested: 1) information on how the term "preexisting condition" is defined in state law; 2) examples of how this definition is applied differently to various products that are applicable to Model #171; and 3) feedback on how Section 7—Preexisting Conditions of Model #170 applies or does not apply to the policy definition of "preexisting condition" in Section 5L of Model #171. She said she received comments from several states, which she has included in a chart posted on the Subgroup's web page. The Subgroup also received comments from America's Health Insurance Plans (AHIP), the Health Benefits Institute (HBI) and the NAIC consumer representatives. These comment letters also are posted on the Subgroup's web page.

Ms. Arp asked for clarity about the term "preexisting condition" in Section 5L. Chris Petersen (Arbor Strategies LLC) explained that there appeared to be some confusion among Subgroup members when this term was discussed in 2019. He said the Subgroup should be cognizant of the fact that Section 5 is not a typical "definitions" section. He said Section 5 is a policy definitions section, which means the terms "defined" in this section are terms that can be used in policies subject to Model #171's requirements. The terms in Section 5 are not terms necessarily used in Model #171, but terms that, if included in a policy subject to Model #171's requirements, the insurer must "define" those terms in the policy consistent with the way the term is "defined" in Section 5 or consistent with state law requirements if those requirements are different from Model #171's requirements. The Subgroup discussed the potential implications with taking certain approaches to revising the term "preexisting condition" based on stakeholder comments, including the use of the prudent layperson standard or a more objective definition of the term to make it easier for consumers to understand.

Noting that it has been a while since the Subgroup last met, Ms. Arp suggested the Subgroup set a new public comment period ending July 2 to receive comments from stakeholders on Sections 1–7 of Model #171. She said stakeholders who have already submitted comments on those sections may resubmit those comments or submit new comments. She said the Subgroup would meet sometime in mid-July to resume its discussion of revisions to Model #171 based on the comments received by the July 2 public comment deadline. Mr. Petersen reminded the Subgroup that Model #170 has been adopted by the full NAIC membership. He said because of this, during its discussions of revisions to Model #171, the Subgroup should not spend time relitigating provisions already resolved in Model #170. Ms. Arp asked NAIC staff to post a redline version of Model #170 to the Subgroup's web page to assist the Subgroup in its discussions.

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

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

### **Summary Report**

The Employee Retirement Income Security Act (ERISA) (B) Working Group plans to meet July 30 in open session to discuss any updates to the *Health and Welfare Plans Under the Employee Retirement Income Security Act: Guidelines for State and Federal Regulation* (ERISA Handbook) related to the U.S. Supreme Court's decision in *Rutledge vs. the Pharmaceutical Care Management Association (PCMA)* with respect to any ERISA preemption. The Working Group also will discuss the *Rutledge* decision in relation to the Pharmacy Benefit Manager Regulatory Issues (B) Subgroup's new 2021 charge to develop a white paper discussing state laws regulating pharmacy benefit manager (PBM) business practices. Following these discussions, the Working Group plans to adjourn into regulator-to-regulator session, pursuant to paragraph 3 (specific companies, entities or individuals) of the NAIC Policy Statement on Open Meetings.

*Virtual Meetings*

**MENTAL HEALTH PARITY AND ADDICTION EQUITY ACT (MHPAEA) (B) WORKING GROUP  
July 20, 2021 / April 21, 2021**

**Meeting Summary Report**

The Mental Health Parity and Addiction Equity Act (MHPAEA) (B) Working Group met July 20, 2021, in a regulator-to-regulator session pursuant to paragraph 2 (pending investigations which may involve either the NAIC or any member in any capacity), paragraph 3 (specific companies, entities or individuals) and paragraph 8 (consideration of strategic planning issues) of the NAIC Policy Statement on Open Meetings. The Working Group also met April 21, 2021, to receive an update from the U.S. Department of Labor (DOL) and the federal Centers for Medicare & Medicaid (CMS) on their work related to the recently enacted federal Consolidated Appropriations Act of 2021 (CAA), which amended the MHPAEA to provide important new protections. In anticipation of new 2021 charges from the Special (EX) Committee on Race and Insurance, the Working Group also discussed equity and diversity in the mental health/substance use disorder treatment context. The Working Group plans to meet Aug. 5 to hear a provider perspective on mental health parity.

Draft: 5/18/21

Mental Health Parity and Addiction Equity Act (MHPAEA) (B) Working Group  
Virtual Meeting  
April 21, 2021

The MHPAEA (B) Working Group of the Regulatory Framework (B) Task Force met April 21, 2021. The following Working Group members participated: Katie Dzurec, Chair (PA); Jane Beyer, Vice Chair (WA); Crystal Phelps (AR); Erin Klug (AZ); Sheirin Ghoddoucy (CA); Cara Cheevers (CO); Kurt Swan (CT); Howard Liebers (DC); Sarah Crittenden (GA); Andria Seip (IA); Ryan Gillespie and Erica Weyhenmeyer (IL); Julie Holmes (KS); Erica Bailey (MD); Andrew Kleinendorst (MN); Jeannie Keller (MT); Rosemary Gillespie, Tracy Biehn and Kathy Shortt (NC); Sara Gerving and Chrystal Bartuska (ND); Tyler Brannen and Michelle Heaton (NH); Ralph Boeckman (NJ); Paige Duhamel and Viara Ianakieva (NM); Todd Oberholtzer, Kyla Dembowski, Molly Mottram, Theresa Schaefer and Marjorie Ellis (OH); Mike Rhoads, Teresa Green and Cuc Nguyen (OK); Alyssa Metivier (RI); Kendall Buchanan (SC); Jill Kruger (SD); Rachel Bowden (TX); Tanji J. Northrup (UT); Brant Lyons (VA); Barbara Belling (WI); Joylynn Fix (WV); and Tana Howard (WY).

1. Received Updates from the DOL and the CCIIO

Amber Rivers (U.S. Department of Labor—DOL) discussed the federal Consolidated Appropriations Act of 2021 (CAA), which amended the MHPAEA to provide important new protections. She said one of the main new protections is a requirement in the CAA to expressly require group health plans and health insurance issuers offering group or individual health insurance coverage that offer both medical/surgical (M/S) benefits and mental health or substance use disorder (MH/SUD) benefits and that impose non-quantitative treatment limitations (NQTLs) on MH/SUD benefits to perform and document their comparative analyses of the design and application of NQTLs.

Ms. Rivers explained that in addition, beginning 45 days after the date of enactment of the CAA, these plans and issuers must make their comparative analyses available to the DOL, the U.S. Department of Health and Human Services (HHS), and the U.S. Department of the Treasury (Treasury Department) (collectively, “the Departments”) or applicable state authorities, upon request. She said under the CAA, the Departments must request a plan or issuer to submit comparative analyses for plans that involve potential MHPAEA violations or complaints regarding noncompliance with the MHPAEA that concern NQTLs and any other instances the Departments determine appropriate. After review of the comparative analyses, the Departments must share information on findings of compliance and noncompliance with the state where the plan is located or the state where the issuer is licensed to do business.

Ms. Rivers said given the shared responsibilities in the CAA between the Departments and the states, the Departments recently released a set of frequently asked questions (FAQ) about MH/SUD parity implementation and part 45 of the CAA, which can be found on the DOL website at this link: <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebbsa/our-activities/resource-center/faqs/aca-part-45.pdf>. She highlighted a few key points in the FAQ document, including guidance on what a sufficient comparative analysis would include and examples of reasons the Departments might find a comparative analysis to be insufficient. The FAQ document also highlights the fact that the state insurance regulators can request a copy of a plan’s or issuer’s comparative analysis. Ms. Rivers said the FAQ document also notes the DOL’s intent to focus on four areas when making a request for a plan’s comparative analysis, including prior authorization, standards for participation in a provider network, and reimbursement rates.

Mary Nugent (Center for Consumer Information and Insurance Oversight—CCIIO) expressed support for Ms. Rivers’ comments about the importance of the CAA in providing new protections related to MHPAEA parity compliance. She noted that the recently issued FAQ document that Ms. Rivers discussed was developed and issued jointly by the Departments. As such, the HHS will be using them as a guidance as it moves forward with implementing the CAA’s NQTL comparative analysis review requirements. Ms. Nugent explained that moving forward, due to overlapping jurisdiction, the HHS anticipates that the states will generally continue to enforce the MHPAEA parity requirements, including the CAA’s new NQTL comparative analysis requirements. The HHS will continue to enforce the MHPAEA parity requirements in the three states it currently has enforcement authority over.

2. Heard a Discussion on Equity and Diversity in the MH/SUD Treatment Context

Ms. Dzurec said the Working Group’s next agenda item concerns a proposed new 2021 charge to the Working Group from the Special (EX) Committee on Race and Insurance to “develop model educational material for state departments of insurance

(DOIs) and research disparities in and interplay between mental health parity and access to culturally competent care for people of color and other underrepresented groups.” She said the Working Group included this item on the agenda in preparation for working on this new charge.

Kris Hathaway (America’s Health Insurance Plans—AHIP) discussed AHIP’s health equity activities as a precursor to additional conversations with the Working Group in the future. She highlighted three AHIP proactive strategies—promoting behavioral health integration, value-based mental health care, and the effective use of technology. She noted the substantial increase in the use of telehealth for the provision of mental health services during the past year. She said because of this, some of AHIP’s member plans have been looking at how to provide access to telehealth services for those plan enrollees who would lack the technology to do so, such as setting up private cubicles in community centers for telehealth visits with providers. She also touched on AHIP’s health equity activities, particularly a new initiative, “Project Link,” which is a collaborative partnership initiative examining social determinants of health to find ways and best practices to effectively address social barriers to good health. She also briefly discussed current AHIP health equity workstreams. One of the workstreams is examining approaches to collecting demographic data from plan enrollees in a culturally sensitive way. Ms. Hathaway also discussed the work of AHIP’s Health Equity Measures Value-Based Care Work Group. She highlighted the work AHIP has been doing with the Blue Cross Blue Shield Association (BCBSA) regarding the Vaccine Community Connectors program, which is a program seeking to reduce vaccination disparities for individuals over 65 in the most vulnerable and underserved communities, such as Black and Hispanic communities. She reiterated AHIP’s willingness to make subject matter experts (SMEs) available to speak to the Working Group in more detail about AHIP’s health equity activities that she just highlighted.

Andrew Sperling (National Alliance on Mental Illness—NAMI) discussed findings from studies already conducted underscoring the link between mental health and race and health disparities, particularly the findings from a study trying to determine the state-of-the-art treatment for schizophrenia. He also discussed a large mental health study conducted by a former U.S. Surgeon General documenting the slow pace in which the mental health/behavioral health field was addressing cultural competence and care as well as the wide disparities that exist there in terms of exploring cultural competence and defining cultural conflicts, while also ensuring that providers were trained in cultural competence in the way they deliver behavioral health care. He said these challenges and disparities remain today 20 years later, particularly with respect to access to mental health services and the quality of the services provided. He noted NAMI’s commitment to addressing these disparities. He also discussed issues with the lack of precision in diagnosing mental health disorders. He concluded his remarks by underscoring how important it is for providers to be trained in cultural competence to recognize and treat mental health disorders in traditionally underserved groups. He also discussed the challenges with mental health parity compliance and enforcement, given that it is typically complaint driven. He suggested that consumer education is key. He also noted that the CAA could help in this effort because of the involvement of employers in the comparative analysis assessments instead of consumers who may not have the ability to understand the complexity of the parity law to determine if there is a violation and file a complaint. He pledged NAMI’s assistance in helping the Working Group work on its proposed new 2021 charge, particularly in assisting the Working Group to invite diverse voices to speak during its future meetings to gain the perspective of racial and ethnic minorities in the country.

Jennifer Nowak (BCBSA) said Blue Cross Blue Shield (BCBS) companies are committed to improving the quality of care, while providing access to effective treatment for substance use disorders. The BCBSA has been developing centers of excellence programs for over 30 years, always with a strong focus on quality and evidence-based care. Ms. Nowak said when the BCBSA began to develop its first center of excellence program focused on mental health/behavioral health, Blue Distinction Centers for Substance Use Treatment and Recovery (BDC SUTR), the BCBSA found that this is a very different landscape than medical and surgical health care, such as the extreme variations in the quality of care delivered and significant differences in providers using evidence-based treatments. These findings heightened the need to build a center of excellence program that enables BCBS members to find resources and identify and access quality providers using evidence-based treatments.

Ms. Nowak discussed the work of BCBS companies’ National Health Equity Strategy (Strategy), which aims to confront the country’s crisis in racial health disparities and intends to change the trajectory of health disparities and re-imagine a more equitable health care system. This Strategy includes: 1) collecting data to measure disparities; 2) scaling effective programs; 3) working with providers to improve outcomes and address unconscious bias; and 4) influencing policy decisions at the state and federal levels.

Ms. Nowak said this multi-year Strategy will focus on four conditions that disproportionately affect communities of color—maternal health, behavioral health, diabetes and cardiovascular conditions. She said the BCBSA will focus first on maternal health, and it intends to focus on behavioral health later this year. She said to assist it in working on the Strategy, the BCBSA convened a national advisory panel of doctors, public health experts, and community leaders to provide guidance.

Lastly, Ms. Nowak discussed BCBS plan examples to address health inequities and behavior health services, such as the Blue Shield of California's partnership with ScaleLA Foundation, the Center for Youth Wellness, and the Compton Unified School District. The goal of this partnership is to develop and implement initiatives that fill behavioral health gaps in care for adolescents, teens and families in Compton and Premera Blue Cross' development of public-private partnerships to fund capital grants supporting crisis care and stabilization and ensuring that people are treated at the appropriate level of care.

Ms. Dzurec noted that at certain points, maternal health can be mental health. As such, the BCBSA's Strategy initiative to focus first on maternal health is not completely outside the Working Group's focus at this point in its discussions, particularly when discussing integrated care. She asked for additional comments. Daniel Blaney-Koen (American Medical Association—AMA) discussed the disparities in access to and the provision of MH/SUD services for people of color. He discussed specific examples of the differences in treatment for people of color and whites having the same substance use disorder issues. He said this type of structural racism and other issues leading to disparities in treatment and services is pervasive throughout the health care system. He also said some of these disparities could be a result of parity issues in areas such as prior authorization requirements and inadequate provider networks. He offered suggestions for the Working Group to consider in looking at this issue, including the importance of collecting demographic data to pinpoint what problems are leading to this disparity.

Ms. Beyer asked Ms. Hathaway about the challenges plans have in trying to collect demographic data from plan enrollees and the extent of this information being available in state all-payer claims databases (APCDs). She noted that in discussing the data issue with Washington's APCD, the APCD suggested linking with census tracks because census tracks include race and ethnicity demographic data. Ms. Hathaway reiterated the challenges plans have in obtaining the data from plan enrollees, including a plan's ability to collect such data on a state-by-state basis. She suggested that the Working Group might want to first focus on the obstacles to obtaining the necessary demographic data and look at possibly utilizing APCDs later in the discussions. She said AHIP is asking how some of its members have been able to obtain demographic data at higher rates, and it is looking at potentially developing a set of best practices to assist all carriers in obtaining such data.

Ms. Dzurec asked Working Group members to submit any thoughts and/or suggestions concerning any research, tools and educational materials for the Working Group to consider as it moves forward with working on its proposed new 2021 charge.

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

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## **PHARMACY BENEFIT MANAGER REGULATORY ISSUES (B) SUBGROUP**

### **Summary Report**

The Pharmacy Benefit Manager Regulatory Issues (B) Subgroup of the Regulatory Framework (B) Task Force has not met since Oct. 29, 2020, because it has completed its work in developing the proposed new [State] Pharmacy Benefit Manager Licensure and Regulation Model Act. The Subgroup plans to resume meeting soon to work on a new 2021 charge to develop a white paper on issues related to the state regulation of certain pharmacy benefit manager (PBM) business practices. The white paper also will examine the role PBMs, pharmacy services administrative organizations (PSAOs), and other prescription drug supply chain entities, play in the provision of prescription drug benefits.

### **Agenda Item #3**

#### **Hear a Work Status Update:**

- **ERISA (B) Working Group—*Jolie Matthews (NAIC)***
- **Pharmacy Benefit Manager Regulatory Issues (B) Subgroup—*TK Keen (OR)***

## **Agenda Item #4**

**Hear an Update on the Center on Health Insurance Reforms' (CHIR's) Work  
Related to the Federal Affordable Care Act (ACA)**

**—Christine Monahan (CHIR, Georgetown University's McCourt School of Public Policy)**

# Update on Georgetown CHIR's Recent and Forthcoming Work

National Association of Insurance Commissioners  
Regulatory Framework (B) Task Force  
July 28, 2021

Christine H. Monahan, J.D.  
Assistant Research Professor



# Recent Publications

- 50-state survey of state employee health benefit plans and efforts to restrain health care cost growth
- State actions to expand telemedicine access during COVID-19 and future policy considerations



# Research Coming Out Soon

- Standardized plans
- Limited plan sales
- State “Easy Enrollment” programs
- Efforts by select SBMs to reduce health inequity
- Small group health insurance market trends



# In the Works: More on Cost Containment

- **NSA implementation (stay tuned!)**
  - Technical assistance available
- **Federal and state public options**
  - Technical assistance available
- **Role of ERISA**
  - Input welcome

# Thank you

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**Agenda Item #5**

**Hear Presentation on the Federal No Surprises Act Interim Final Regulations**

**—*Katie Keith (Out2Enroll) and Jack Hoadley (Georgetown University Health Policy Institute)***



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**Implementing the No Surprises Act:  
Implications for States**

**NAIC Regulatory Framework Task Force**

July 28, 2021

Jack Hoadley and Katie Keith

# About Georgetown's Center on Health Insurance Reforms (CHIR)

- A team of experts on private health insurance and health reform
- Conduct research and policy analysis, provide technical assistance to federal and state officials and consumer advocates
- Based at Georgetown University's McCourt School of Public Policy
- Learn more at <https://chir.georgetown.edu/>
- Subscribe to CHIRblog at <http://chirblog.org/>
- Follow us on Twitter @GtownCHIR



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# No Surprises Act: An Overview

- Public Law 116-260, signed December 27, 2020
  - Included in the Consolidated Appropriations Act, 2021
- Most provisions are effective for plan years beginning on or after January 1, 2022
- Bars out-of-network bills in emergency and certain non-emergency situations and by air (but not ground) ambulances
  - Patients responsible for in-network cost sharing only
  - Cost sharing payments count toward the in-network deductible and out-of-pocket limit
- Federal officials must undertake significant amount of rulemaking and create new systems for complaints and independent dispute resolution (IDR)



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# Federal Rulemaking Process

- First quad-agency interim final rule (IFR) released on July 1, 2021
  - Issued by HHS, Treasury, Labor, and OPM
  - Included draft standard notice and consent waivers, model disclosures for patients
  - Effective date of the IFR: September 13, 2021
- IFR focused on both patients and regulated entities
  - Patient-focused provisions = how to calculate cost-sharing, notice-and-consent waivers, complaints process
  - Regulated entities-focused provisions = how to calculate the qualifying payment amount, disclosure requirements, communication between insurers and providers
- More federal rules are coming (more to come on that)



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# Scope of Protections: Insurers

- The No Surprises Act **applies** to:
  - Health insurers offering group or individual health insurance coverage
  - Grandfathered and grandmothered (or transitional) plans or policies
  - Student health insurance
  - Traditional indemnity plans
  - Self-funded group health plans
  - Non-federal governmental plans
  - Church plans
  - Federal Employees Health Benefits Program coverage
- The No Surprises Act **does *not* apply** to:
  - Short-term limited duration insurance, excepted benefits, account-based plans (e.g., HRAs), retiree-only plans



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# Scope of Protections: Providers

- **Emergency care provided in in-network or out-of-network facilities**
  - Statute includes EDs and independent free-standing EDs
  - IFR extends to urgent care centers licensed by state for emergency services
- **Post-stabilization services until the patient can travel using nonmedical or non-emergency medical transportation**
  - Protections apply regardless of *where* in a hospital the services are furnished
  - Strong patient protections for waivers in these circumstances - patient must be able to travel using nonmedical/nonemergency transportation, patient gives informed consent, in-network facility is within a reasonable distance, no unreasonable travel burdens, etc.
- **Air ambulance services**
  - Includes helicopters, fixed-wing air ambulances, inter-facility transports
  - Includes plans or coverage that cover air ambulance benefits (even if no current in-network air ambulance providers)



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# Scope of Protections: Providers

- **Non-emergency care at in-network facilities provided by out-of-network providers**
  - Definition of health care facility
    - Statute defines facilities as hospitals, hospital outpatient departments, critical access hospitals, and ambulatory surgical centers
    - IFR does not identify additional types of facilities but poses questions about urgent care centers, retail clinics
  - Definition of in-network facility as direct/indirect contractual relationship with a plan or issuer for nonemergency care
    - IFR: single case agreements are included
  - Protections extend to the entire “visit” to an in-network facility
    - Includes devices, imaging services, lab services, etc. for in-network care even if those services are provided by out-of-network providers



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# Notice and Consent Provisions

- Patients can knowingly and voluntarily agree to be balance billed by out-of-network providers but only for:
  - *Non-emergency* care from an out-of-network provider
  - Out-of-network *post-stabilization* services
- Protections **cannot** be waived:
  - When there is no in-network provider available
  - For urgent or unforeseen care
  - When services are delivered by providers in designated specialties, e.g., anesthesiology, radiology, hospitalists, intensivists
    - IFR did not identify additional providers that cannot ask for a waiver
  - For post-stabilization services except as noted above



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# Notice and Consent Provisions

- Statute requires at least 72-hour advance notice for consent waivers
  - IFR clarifies that consent must be obtained at least 3 hours before time of appointment if appointment occurs within 72 hours of scheduling
- Content of the notice and when it must be obtained
  - E.g., Providers and facilities must include a good-faith cost estimate, inform patients of the option to seek or ask for in-network care, and provide a list of in-network providers at the facility
  - E.g., Forms must be translated into 15 most common languages in the state (with some flexibility) and cannot be buried with other documents
  - E.g., Patients can refuse to provide or revoke consent at any time
- IFR accompanied by a draft standard notice and consent form
  - Seeking comment; interest in potential models in use by states



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# Qualifying Payment Amount

- Defined in statute as the median of the plan or insurer's contracted rates for the item or service in that geographic region
- Relevant as the basis for cost sharing (coinsurance and under the deductible) where no specified state law applies
- Used as a factor in the federal IDR process
- IFR spells out definitions and methodology
  - Minimizes influence of outlier prices that could skew QPA higher
  - Reduces need to rely on alternative methods to calculate QPA where insurer has insufficient information
  - Did not choose adopt to base regions on QHP rating areas
  - Uses larger regions based on MSAs and non-MSA areas in a state



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# Specified State Laws

- “Specified state law” is one that provides for a method for determining the amount of payment to an out-of-network provider (whether payment standard or arbitration)
  - State method used to determine payments for health plans regulated by the state and services to which state law applies
  - State method also used to determine cost-sharing amounts
- **IFR:** States with self-funded opt-in programs can maintain those programs
- If state law does not apply, the No Surprises Act applies
  - Cost sharing will be lesser of the QPA or a provider’s billed charges
  - Payment disputes will be resolved under the federal IDR process



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# Enforcement on Insurers

- State departments of insurance are the primary enforcers of provisions that apply to insurers and fully insured health products
- Federal government enforces in states that fail to substantially enforce the law (HHS) and for self-funded group health plans (DOL)
- HHS proposes a consolidated complaints process for patients that have been balance billed
  - Seamless way to file complaints, without a patient needing to know whether their balance bill falls under state or federal jurisdiction



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# Enforcement on Providers

- Same framework for enforcing the provisions that apply to providers (including air ambulances)
  - State officials are responsible for enforcing the provisions against providers but HHS will do so where a state chooses not to or fails to substantially enforce the law
  - HHS can impose civil monetary penalties of up to \$10,000 per violation if a provider sends a balance bill that violates the law (penalties can be waived in certain circumstances)
- Law is silent on which state agency is responsible for enforcing provider provisions - unless addressed through rulemaking



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# Other Issues Addressed in the IFR

- Regulated entities must comply with new notice requirements:
  - Post a publicly available notice about the NSA's protections on websites and on EOBs for out-of-network care
  - Prominently display this information in a publicly accessible location (for providers and facilities)
  - IFR accompanied by a draft model disclosure form → Urges states to develop model language to convey state-specific requirements
  - Air ambulances do not have to make the same disclosure but are encouraged to provide clear, understandable info about the law
- Guardrails on initial payment amount for out-of-network services
- Disclosures about the QPA



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# Key Considerations for States

- **Scope of Protections.** State laws can be more consumer protective, as long as they don't "prevent the application of federal law."  
Example provisions where some state laws differ
  - IFR clarifies that state provisions that do not allow waiver of protections by the consumer are allowed
  - IFR recognizes that state laws vary on the scope of providers covered (out-of-network facilities, certain specialties)
  - Federal law is generally more protective for post-stabilization services
- **Enforcement.** Are states prepared to enforce these requirements on both insurers and providers (including air ambulance providers)?



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# Key Considerations for States

- **Specified State Law.** Which state laws qualify as a “specified state law” and when would they apply? IFR determines applicability in specific scenarios, such as:
  - Federal method applies for items or services not state regulated
  - Federal method applies for claims involving multiple states
  - State method applies where laws allows opt-in by ERISA plans
- **Cost Sharing Protections.** Cost sharing is also determined under state laws
  - Especially relevant for coinsurance and under deductibles
  - Do states allow arbitration decisions to change cost sharing?
  - Do state rules for in-network medians rates differ from federal QPA?



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# Future Steps for Implementation

- We anticipate **at least two more rules** in 2021:
  - Independent dispute resolution process (interim final rule)
  - Enforcement and air ambulance data reporting (proposed rule)
- Additional rulemaking will occur over time on other No Surprises Act requirements such as accurate provider directories, gag clauses, PBM reporting requirements, etc.
  - No rulemaking before 2022 effective date, but entities must still comply and adopt a good faith, reasonable interpretation of the statute



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# Resources

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Katie Keith, Associate Research Professor,

[katie.keith@georgetown.edu](mailto:katie.keith@georgetown.edu)

Georgetown University Center on Health Insurance Reforms

Website: <https://surprisemedicalbills.chir.georgetown.edu/>

Health Affairs blog on IFR:

<https://www.healthaffairs.org/doi/10.1377/hblog20210706.903518/full/>

Commonwealth Fund blog with link to detailed summary of law:

<https://www.commonwealthfund.org/blog/2020/surprise-billing-protections-cusp-becoming-law>

Website on surprise medical bills:

<https://surprisemedicalbills.chir.georgetown.edu/>



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**Agenda Item #6**

**Discuss Any Other Matters Brought Before the Task Force**  
**—*Commissioner Michael Conway (CO)***