**AGENDA**

1. Consider Adoption of its March 18 and March 1, 2021, and Nov. 19, 2020, Minutes  
   —Commissioner Michael Conway (CO)

2. Consider Adoption of its Subgroup and Working Group Reports  
   a. Accident and Sickness Insurance Minimum Standards (B) Subgroup  
      —Commissioner Glen Mulready (OK) and Laura Arp (NE)  
   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 an Update on the Center on Health Insurance Reforms’ (CHIR’s) Work Related to the Federal Affordable Care Act (ACA)—Justin Giovannelli (CHIR, Georgetown University Health Policy Institute)

4. Hear Presentation on Federal No Surprises Act: Impact on the States—Jack Hoadley (Georgetown University Health Policy Institute) and Kevin Lucia (Georgetown University Health Policy Institute)

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5.  Hear a Discussion of the Decision in Rutledge vs. Pharmaceutical Care Management Association (PCMA) —Katie Keith (Out2Enroll)

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

7.  Adjournment
Agenda Item #1

Consider Adoption of its March 18 and March 1, 2021 and Nov. 19, 2020 Minutes
—Commissioner Michael Conway (CO)
The Regulatory Framework (B) Task Force met March 18, 2021. The following Task Force members participated: Michael Conway, Chair (CO); Bruce R. Ramge, Vice Chair, represented by Laura Arp and Martin Swanson (NE); Lori K. Wing-Heier represented by Sarah Bailey (AK); Jim L. Rutledge represented by Anthony L. Williams, Jimmy Gunn and Yada Horace (AL); Evan G. Daniels represented by Jon Savary and Erin Klug (AZ); Ricardo Lara represented by Bruce Hinze and Sheirin Ghodssi (CA); Andrew M. Mais represented by Jared Kosky (CT); Karima M. Woods (DC); David Altmaier represented by Chris Struk (FL); Doug Ommen represented by Andria Seip, Sonya Sellmeyer and Cynthia Banks Radke (IA); Dean L. Cameron (ID); Dana Popish Severingham represented by Shannon Whalen (IL); Stephen W. Robertson represented by Claire Szpara (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 Renee Campbell (MI); Grace Arnold represented by Galen Benshoof and Candance Gergen (MN); Chlora Lindley-Moore (MO); Mike Causey represented by Robert Croom (NC); Jon Godfread represented by Chrystal Bartuska (ND); Chris Nicolopoulos represented by Michelle Heaton and Jason Dexter (NH); Marlene Caride represented by Philip Gennace (NJ); Judith L. French represented by Laura Miller (OH); Glen Mulready represented by Andrew Schallhorn and Mike Rhoads (OK); Andrew R. Stolfi (OR); Jessica K. Altman (PA); Larry D. Deiter (SD); Doug Slape represented by Rachel Bowden (TX); Jonathan T. Pike represented by Tanji J. Northrup and Jaakob Sundberg (UT); Scott A. White represented by Don Beatty, Stephen Hogge, Bob Grissom and James Young (VA); Mike Kreidler represented by Molly Nollette (WA); Mark Afable represented by Nathan Houdek, Richard Wicka and Jennifer Stegall (WI); and James A. Dodrill represented by Ellen Potter (WV).

1. **Adopted the PBM Model Act**

Commissioner Conway said that during the Task Force’s March 1 meeting, the Task Force heard from various stakeholders who had submitted comments on the draft [State] Pharmacy Benefit Manager Licensure and Regulation Model Act (PBM model). He explained that following that meeting, NAIC staff had revised the draft PBM model to add additional relevant state statutory citations suggested in the some of the comment letters. He asked the Task Force members if anyone had any suggestions for additional revisions.

Commissioner Schmidt asked if Commissioner Conway had considered adding a reference to the *Rutledge v. Pharmaceutical Care Management Association* (PCMA) case in the Section 8—Regulations drafting note. Commissioner Conway said he asked NAIC staff if such references are typically included in NAIC models. He said NAIC staff said such language is not typically included. He also said that he anticipates more litigation involving state pharmacy benefit manager (PBM) regulation and because U.S. Supreme Court (Court) decisions tend to evolve over time, including a reference to this case could possibly be misleading in the future because stakeholders could be led to believe that the *Rutledge* case is the only relevant case when the Court could issue future decisions on the subject. Commissioner Conway also reiterated his support for further discussion of the *Rutledge* decision, but he suggested that the better setting for such a discussion would be in the proposed white paper, which the Task Force discussed charging the Pharmacy Benefit Manager Regulatory Issues (B) Subgroup with developing during its March 1 meeting.

Commissioner Stolfi made a motion, seconded by Mr. Hinze, to adopt the [State] Pharmacy Benefit Manager Licensure and Regulation Model Act (Attachment One-A). The motion passed, with Connecticut and North Dakota voting against the motion.

Commissioner Conway asked NAIC staff about the Task Force’s next steps to charge the Pharmacy Benefit Manager Regulatory Issues (B) Subgroup with developing the white paper as has been discussed. Jolie H. Matthews (NAIC) said the Task Force will need to develop and adopt a new 2021 Subgroup charge prior to the Subgroup beginning its work. She said the Health Insurance and Managed Care (B) Committee also would have to adopt the charge.

Mr. Kosky explained that Connecticut voted against the motion because of concerns with the Section 8 drafting note’s menu of options. He said Connecticut was concerned that the language in the drafting note could lead to inconsistency and the lack of uniformity in state adoption of the NAIC model. He said this potential lack of uniformity and standardization of language would appear to go against the NAIC’s goal when adopting NAIC models. He also expressed concern about setting a precedent. Mr. Kosky expressed support for developing a white paper and the white paper as the more appropriate vehicle to describe state options concerning PBM regulation rather than an NAIC model. Commissioner Conway said he believes some states will...
add provisions beyond the PBM model’s core licensing provisions, but he believes the PBM model is a good work product with substantive core provisions that will be helpful to the states. He acknowledged that there is probably more work to be done on the menu of options in the Section 8 drafting note and that there will probably be discussion on whether the menu of options should remain in the NAIC model or be made part of the white paper.

Commissioner Schmidt noted that many state legislatures are moving forward with legislation to license or register PBMs with or without a NAIC model. She said there most likely will be no uniformity among the states as things are currently advancing in the states. She also noted how rapidly things are changing with respect to the state regulation of PBMs. She also agreed with Commissioner Conway that the Rutledge decision most likely will not be the last U.S. Supreme Court decision affecting the state regulation of PBMs, but she said she believes the PBM model is the best effort at this time.

Commissioner Altman said Pennsylvania voted in favor of the motion to move the discussion forward on the PBM model to the Health Insurance and Managed Care (B) Committee, but she also has concerns similar to Connecticut’s concerns about the Section 8 drafting note and its menu of options. She said she does not know how Pennsylvania will vote on the PBM model moving forward, but Pennsylvania strongly supports developing the white paper. Commissioner Conway acknowledged her comments. He said he agrees that the Section 8 drafting note will be a point of discussion as the PBM model moves forward, particularly because the Task Force has agreed to move forward with the white paper.

Having no further business, the Regulatory Framework (B) Task Force adjourned.
The Regulatory Framework (B) Task Force met March 1, 2021. The following Task Force members participated: Michael Conway, Chair (CO); Bruce R. Ramge, Vice Chair, and Laura Arp (NE); Lori K. Wing-Heier represented by Sarah Bailey (AK); Jim L. Ridling (AL); Evan G. Daniels represented by Erin Klug (AZ); Ricardo Lara represented by Bruce Hinze and Tyler McKinney (CA); Andrew M. Mais represented by Jared Kosky (CT); David Altmaier represented by Chris Struk and Shannon Doheny (FL); Doug Ommen (IA); Dean L. Cameron represented by Kathy McGill (ID); Dana Popish Severinghaus represented by Eric Anderson and Kate Morthland (IL); Stephen W. Robertson represented by Karl Knable, Alex Peck and Claire Szpara (IN); Vicki Schmidt (KS); Sharon P. Clark (KY); Gary D. Anderson represented by Kevin Beagan (MA); Eric A. Cioppa represented by Robert Wake (ME); Grace Arnold represented by Eric Taubel (MN); Chlora Lindley-Myers (MO); Mike Causey represented by Robert Croom (NC); Jon Godfread represented by Angie Voegele (ND); Chris Nicolopoulos represented by Maureen Belanger (NH); Marlene Caride (NJ); Judith L. French represented by Theresa Schaefer, Laura Miller and Marjorie Ellis (OH); Glen Mulready represented by Andrew Schallhorn and Kim Bailey (OK); Andrew R. Stolli represented by TK Keen (OR); Jessica K. Altman represented by Michael Humphreys and Katie Dzurec (PA); Larry D. Deiter represented by Jill Kruger and Candy Holbrook (SD); Doug Slape represented by Rachel Bowden and Doug Danzeiser (TX); Jonathan T. Pike (UT); Scott A. White represented by Don Beatty (VA); Mike Kreidler represented by Molly Nollette (WA); Mark Afable represented by Nathan Houdak, Richard Wicka and Jennifer Stegall (WI); and James A. Dodrill represented by Joylynn Fix and Ellen Potter (WV). Also participating was: Troy Downing (MT).

1. Discussed Comments Received on the Draft PBM Model Act

Commissioner Conway said the main purpose of today’s meeting is for the Task Force to discuss the comments received on the draft [State] Pharmacy Benefit Manager Licensure and Regulation Model Act (PBM model). He explained that the Pharmacy Benefit Manager Regulatory Issues (B) Subgroup adopted the draft PBM model late last year after an extensive, open drafting process. The Subgroup presented the draft PBM model to the Task Force for its consideration during a meeting last November. The Task Force decided to defer adoption of the model and open the model for a public comment period ending Dec. 22, 2020.

Commissioner Conway said the Task Force received seven comment letters from various stakeholders—America’s Health Insurance Plans (AHIP), the Blue Cross and Blue Shield Association (BCBSA), the Health Benefits Institute (HBI), the HIV+HEP Policy Institute, NAIC consumer representatives, the National Community Pharmacists Association (NCPA) and the Pharmaceutical Care Management Association (PCMA). He said each of the commenters have been given opportunity to provide an overview of their written comments to the Task Force. He said that at the end of this discussion, he plans to discuss the Task Force’s next steps, which most likely will involve discussion of the Section 8—Regulations drafting note and the impact, if any, of the U.S. Supreme Court’s decision in Rutledge vs. Pharmaceutical Care Management Association (PCMA) on the drafting note.

Kris Hathaway (AHIP) said AHIP supports the PBM licensing and registration requirements and the gag clause prohibition provisions in the draft PBM model. However, AHIP remains concerned with some of the provisions included within the draft PBM model, including the Section 8 drafting note and Section 6—Gag Clauses and Other Pharmacy Benefit Manager Prohibited Practices gag clause language. Ms. Hathaway said that specifically, AHIP believes provisions within the Section 8 drafting note language would significantly increase overall health care costs. She said other provisions in the drafting note are not clearly defined and appear to exceed the scope of the draft PBM model. Ms. Hathaway said that with respect to the gag clause language in Section 6, AHIP continues to encourage adoption of the federal gag clause language that was heavily debated and advanced with broad-based stakeholder support and more than 30 states have adopted rather than the language in Section 6, which has only been adopted by one state. She also said that if it is contemplated that additional work needs to be done considering the Rutledge decision, then the Employee Retirement Income Security Act (ERISA) (B) Working Group would be the more appropriate NAIC group to conduct such discussions—not the Pharmacy Benefit Manager Regulatory Issues (B) Subgroup—because expanding the draft PBM model beyond its current language could jeopardize the hard work done to reach consensus.

Haile Dagne (BCBSA) said the BCBSA supports many of the core provisions in the draft PBM model and appreciates the Subgroup’s decision during its drafting process to move the broad language from the initial draft of Section 8B to a drafting
note. He said this decision more closely aligns the draft PBM model with the Subgroup’s charge to consider developing a new NAIC model to establish a licensing or registration process for PBMs within state departments of insurance (DOIs). He said the BCBSA suggests the Task Force consider modifications to the draft as follows: 1) requiring PBMs to notify state insurance regulators of any changes to their application within 90 days of the change and disclosing the list by health insurers and the kinds of health plans (e.g., health maintenance organization [HMO], preferred provider organization [PPO]) administered by pharmacy benefit managers (PBMs) within the state as suggested in Section 8B(10); 2) removing “financial and reporting” from Section 5B—Licensing Requirement and the drafting note suggesting states consider establishing financial standards if the state restricts DOI authority because Section 5 is intended to focus on licensing requirements—not financials or reporting stipulations; 3) modifying the language in Section 6 to mirror the federal gag clause provisions; and 4) deleting Section 6A(4) and Section 6A(5) because these provisions would allow pharmacists to disclose information to which a pharmacist would not have access and could lead to consumer confusion.

Commissioner Conway asked how the BCBSA draws a distinction between Section 6A(3) and Section 6A(4) and Section 6A(5). Mr. Dagne said that Section 6A(3) is limited to a pharmacist disclosing whether a claim is approved or denied (i.e., “the decision of utilization reviewers or similar persons to authorize or deny services”). Section 6A(4) is broader in scope and attempts to disclose information that a pharmacist would not be aware of—“the process that is used to authorize or deny healthcare services or benefits.” He said that such information about the utilization management decision-making process or rationale is not available to pharmacists and that speculating on the process could be confusing to the consumer.

J.P. Wieske (HBI) said that although the draft PBM model is not perfect and the HBI has concerns, it supports the draft PBM model as drafted. He said the draft strikes the right balance with where most states are at this time without being divisive and allows for a lot of flexibility in its design. Mr. Wieske said that he believes the Rutledge decision has no major impact on the draft PBM model, but given its flexibility, those states that may want to explore the possibility of including similar provisions that were the subject of the Rutledge case can do so. He also said the draft PBM model reflects significant compromise from various sides of the issue including pharmacies, pharmacy benefit managers, insurers, and consumer representatives. The HBI supports the draft PBM model in the spirit of compromise.

Carl Schmid (HIV+HEP Policy Institute) discussed the role of PBMs in prescription drug access and availability using drug formularies and establishing prior authorization and other utilization management techniques. He also discussed the increasing role the HIV+HEP Policy Institute believes PBMs play in the high cost of prescription drugs in the U.S. He said the HIV+HEP Policy Institute is disappointed that the draft PBM model does not include provisions related to the second part of the Subgroup’s charge to consider PBM prescription drug pricing and cost transparency. He said that instead of adding a drafting note to Section 8 providing examples of laws passed by states that address many of the important issues involving PBMs, the HIV+HEP Policy Institute believes the Subgroup should have proposed specific language pertaining to: 1) ensuring greater transparency in the work of PBMs; 2) ensuring greater enforcement; 3) establishing that PBMs have a fiduciary relationship with health carriers; and 4) allowing PBMs to pass rebates on to consumers. Mr. Schmid said the recent Rutledge decision provides more reason for the NAIC to adopt a stronger and clearer PBM model. He also said the HIV+HEP Policy Institute suggests in its comment letter additional state citations to the Section 8 drafting note.

Anna Howard (American Cancer Society Cancer Action Network—ACS CAN), speaking on behalf of the NAIC consumer representatives, said the NAIC consumer representatives are concerned that the draft PBM model will not provide states that wish to go further in their regulation of PBMs with direction and options that may be available to them. She said the NAIC consumer representatives recommend a deeper discussion of these issues and the Subgroup’s development of a white paper to allow the NAIC to: 1) better analyze and assess the role that PBMs play in the provision of prescription drug benefits; and 2) to identify and describe emerging state regulatory approaches that curb the PBM practices that contribute to high drug prices and insurance affordability challenges. The white paper should address the breadth of topics that were ultimately left out of the draft PBM model, including transparency and reporting requirements; fiduciary duty and other business practices provisions; and consumer cost sharing and access. Ms. Howard said the NAIC consumer representatives also suggest reconvening the Subgroup to discuss the implications of the Rutledge decision on the draft PBM model, including any potential changes, particularly given the draft PBM model’s limited scope. She said the NAIC consumer representatives also suggest adding additional state statutory citations to the Section 8 drafting note.

Commissioner Conway asked Ms. Howard what other areas a white paper should focus on in addition to the areas examined in the Rutledge case. Ms. Howard said the white paper should discuss the specific options and model language that states can use that might want to more extensively regulate PBMs, such as the business practices listed in the Section 8 drafting note.
Matthew Magner (NCPA) said the NCPA, and the other signatories to its comment letter, have been concerned for a while about the outsized impact PBMs have had on prescription drug benefits and patient access to pharmacy services. He said PBMs not only administer pharmacy benefits for health plans, but also some own their own pharmacies, which creates a conflict of interest that interferes with the patient-pharmacy relationship and can also raise prescription drug costs for consumers. Mr. Magner said the NCPA believes that given the decision in the Rutledge case, state legislatures will be pursuing legislation to increase PBM oversight in their states. He said the states will be looking to the NAIC’s model to determine how best to accomplish this. As such, the NCPA requests the Task Force consider its suggested amendments to the draft PBM model to better prepare the states to address PBM practices that limit patient access to community pharmacy services and increase prescription drug costs, such as provisions: 1) ensuring pharmacy or patient choice; 2) imposing a fiduciary responsibility between the PBM and the health carrier; and 3) concerning pharmacy audits. Mr. Magner said the suggested amendments reflect provisions enacted in one form or another in one or more states. He said the NCPA also recommends including a reference to the Rutledge decision in the Section 8 drafting note for the states to know where to go to obtain more information about their authority to include such provisions in their laws.

Commissioner Schmidt asked if the NCPA had any comments on the NAIC consumer representatives’ suggestion for the Pharmacy Benefit Manager Regulatory Issues (B) Subgroup to develop a white paper. Mr. Magner said the NCPA supports the development of a white paper and would be happy to participate in the discussions during its development to provide a community pharmacist’s perspective on the issues the white paper will most likely discuss.

Lauren Rowley (PCMA) said the PCMA, along with a variety of interested parties, including representatives of pharmacies and consumer representatives, actively participated in the Subgroup’s work on the draft PBM model. She acknowledged the Subgroup’s work was a deliberative and thoughtful discussion of the comments received, and it worked to reach a compromise on some of the draft PBM model’s provisions. She said that while the compromises in the draft do not necessarily reflect the PCMA’s ideal public policy, it does reflect a reasonable set of compromises across all interested parties. Ms. Rowley said PBMs are not insurers and do not collect premium from beneficiaries. She outlined what services PBMs provide to insurers to deliver safe, cost-effective prescription drug benefits. Ms. Rowley discussed the PCMA’s interpretation of the Rutledge decision, which it believes was a narrow decision. She also said that like AHIP, if there are further discussions related to the decision, the ERISA (B) Working Group would be the appropriate NAIC group to conduct such discussions. Ms. Rowley said the PCMA suggests the Task Force adopt the draft PBM model as drafted by the Subgroup.

Mr. Beatty questioned why discussions of the Rutledge decision should not be discussed by the Pharmacy Benefit Manager Regulatory Issues (B) Subgroup. Ms. Rowley said the PCMA believes the ERISA (B) Working Group’s membership includes those who are well-versed in ERISA and ERISA preemption issues. She said the Court’s decision in Rutledge did not invalidate its previous decisions related to ERISA preemption. She suggested that as such, the ERISA preemption issues should, perhaps, be looked at more broadly to discuss what the Court actually said in the decision and its implications for the states with respect to PBM regulation. Commissioner Conway suggested that there was a role for both the ERISA (B) Working Group and the Pharmacy Benefit Manager Regulatory Issues (B) Subgroup concerning any discussions of the Rutledge decision.

Mr. Keen discussed the Pharmacy Benefit Manager Regulatory Issues (B) Subgroup’s drafting process, including the Subgroup’s early work to ensure everyone was equally educated on these issues before it started drafting a model. He explained that the current draft PBM model reflects the differing viewpoints from the Subgroup members with respect to PBM regulation. He said some states currently have robust PBM regulatory schemes, while other states do not currently regulate them. He said this dichotomy of state PBM regulation was evident in the Subgroup’s discussions, with some Subgroup members at the beginning of the drafting process advocating for establishing an elaborate regulatory scheme in the draft with other Subgroup members advocating for a more incremental approach. Mr. Keen said that in developing the model, given this dichotomy, the Subgroup tried to come up with a draft that would be helpful for every state. He said the Subgroup also was mindful that the states wanted an NAIC model on this topic as soon as possible because their legislatures are asking for information and some sort of general framework for regulating PBMs.

Ms. Arp expressed support for Mr. Keen’s comments. She said the Subgroup ultimately ended up with the Section 8 drafting note because of the lack of a consensus among the states on the topics described in the drafting note—not because of concerns with ERISA preemption. As such, the Rutledge decision does not mean the NAIC should restart its work on the draft PBM model. The decision means that a state can consider adding provisions in its laws related to maximum allowable cost (MAC) pricing and not be vulnerable to ERISA preemption. Ms. Arp discussed the uncertainty of other provisions listed in the drafting note on the cost of prescription drugs and the importance of obtaining such information as states move forward with implementing some of them. She also discussed the importance of understanding what the motive or end goal is of regulating PBMs rather than making public policy on Court dicta in a decision.
Mr. Keen said the Subgroup would be supportive of developing a white paper, as has been discussed, if that is what the Task Force decides should be the next step after adoption of the PBM model.

Commissioner Conway said NAIC staff will schedule a meeting prior to its already scheduled March 25 meeting to consider adoption of the draft PBM model. He requested comments from Task Force members. Commissioner Schmidt suggested that the draft PBM model should include a reference to the Rutledge decision. Commissioner Conway acknowledged her suggestion, but he questioned whether the NAIC has included such references in other NAIC models. Mr. Beatty expressed support for Commissioner Schmidt’s suggestion. Commissioner Conway agreed that there needs to be further discussion of the Rutledge decision, but he suggested that the better setting for such a discussion would be in the proposed white paper.

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

Draft: 11/30/20

Regulatory Framework (B) Task Force
Virtual Meeting (in lieu of meeting at the 2020 Fall National Meeting)
November 19, 2020

The Regulatory Framework (B) Task Force met Nov. 19, 2020. The following Task Force members participated: Michael Conway, Chair (CO); Bruce R. Ramge, Vice Chair, represented by Martin Swanson and Laura Arp (NE); Lori K. Wing-Heier represented by Sarah Bailey (AK); Jim L. Ridling represented by Anthony L. Williams and Yada Horace (AL); Alan McClain represented by William Lacy and Mel Anderson (AR); Ricardo Lara represented by Sheirin Ghoddoucy (CA); David Altmaier represented by Chris Struk and Shannon Doheny (FL); Doug Ommen (IA); Dean L. Cameron represented by Weston Trellex and Kathy McGill (ID); Robert H. Muriel represented by Erica Weyhenmeyer (IL); Vicki Schmidt (KS); Sharon P. Clark (KY); Gary Anderson represented by Kevin Beagan (MA); Eric A. Cioppa represented by Robert Wake (ME); Grace Arnold represented by Galen Benshoof (MN); Chlora Lindley-Myers (MO); Mike Causey represented by Ted Hamby (NC); Jon Godfread represented by Chrystal Bartuska (ND); Chris Nicolopoulos represented by Maureen Belanger (NH); Glen Mulready (OK); Andrew R. Stolfi represented by TK Keen (OR); Jessica K. Altman (PA); Larry D. Deiter represented by Jill Kruger (SD); Texas represented by Doug Danzeiser and Rachel Bowden (TX); Tanji J. Northrup represented by Jaakob Sundberg (UT); Scott A. White represented by Jackie Myers and Elsie Andy (VA); Mike Kreidler represented by Kimberly Tocco (WA); Mark Afable represented by Nathan Houdek and Richard Wicka (WI); and James A. Dodrill represented by Tonya Gillespie and Ellen Potter (WV).

1. **Adopted its Oct. 23, Sept. 24, and Summer National Meeting Minutes**

The Task Force met Oct. 23 and Sept. 24. During these meetings, the Task Force adopted its 2021 proposed charges and the revisions to the *Health Maintenance Organization Model Act* (#430).

Commissioner Altman made a motion, seconded by Commissioner Schmidt, to adopt the Task Force’s Oct. 23 (Attachment One), Sept. 24 (Attachment Two), and Aug. 4 (see *NAIC Proceedings – Summer 2020, Regulatory Framework (B) Task Force*) minutes. The motion passed unanimously.

2. **Adopted its Subgroup and Working Group Reports**

Commissioner Altman made a motion, seconded by Ms. Kruger, 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 Health Maintenance Organization (HMO) Issues (B) Subgroup; and the Mental Health Parity and Addiction Equity Act (MHPAEA) (B) Working Group. The motion passed unanimously.

3. **Adopted the Report of the Pharmacy Benefit Manager Regulatory Issues (B) Subgroup**

Mr. Keen said the Pharmacy Benefit Manager Regulatory Issues (B) Subgroup met Oct. 29, Oct. 22, Oct. 8, Oct. 1, Sept. 24 and Sept. 14. He said during these meetings, the Subgroup discussed the comments received on the proposed new [State] Pharmacy Benefit Manager Licensure and Regulation Model Act (PBM model). He said the Subgroup revised the proposed PBM model based on its discussion during these calls. The Subgroup adopted the proposed PBM model on Oct. 29 and agreed to forward it to the Task Force for its consideration.

Mr. Keen discussed the Subgroup’s drafting process. He said after the Subgroup was appointed in late 2018, it decided during its first meetings in early 2019 that it wanted to obtain more information before drafting the new PBM model that regulates pharmacy benefit managers (PBMs) and additional provisions related to PBM prescription drug pricing and cost transparency. He said the Subgroup met 12 times throughout the summer and early fall of 2019 to hear from various stakeholders on the issues the Subgroup wanted to hear more about, such as rebating, discounts, prescription drug pricing, and how PBMs are currently regulated. He said the goal was to have the Subgroup members all equally educated on these issues before it started drafting a model.

Mr. Keen said following the conclusion of these informational meetings, the Subgroup established an ad hoc drafting group to develop an initial draft based on the Subgroup’s discussions. He said after a series of meetings late last year and early this year, the ad hoc drafting group developed a draft for the Subgroup’s review. He said the Subgroup met July 16 to discuss the ad hoc drafting group’s draft and expose the draft for a public comment period ending Sept. 1. The Subgroup received 19 comment...
Draft Pending Adoption

letters, which it discussed during its Oct. 29, Oct. 22, Oct. 8, Sept. 24 and Sept. 14 meetings. After these discussions, the Subgroup adopted the proposed PBM model.

Mr. Keen described some provisions in the proposed PBM model. He explained that at its core, the model is a PBM licensing model. He said given the lack of national consensus on some issues, particularly issues related to PBM transparency, the Subgroup decided on this framework. He said Sections 1 through 4 of the proposed PBM model set out the model’s purpose, scope and definitions. Section 5 provides the PBM licensing provisions, including provisions related to approving initial PBM licenses and renewals.

Mr. Keen said the Subgroup had a lot of discussion concerning Section 6—Gag Clauses and Other Pharmacy Benefit Manager Prohibited Practices. He said the Subgroup received comments from a wide range of stakeholders on this section in terms of the language related to gag clauses and information-sharing for the purposes of enforcement. Section 7 of the proposed PBM model provides enforcement language and penalties for any violations of the model act.

Mr. Keen said the Subgroup spent the bulk of its time discussing the framework for Section 8—Regulations. He explained that the Subgroup decided to add a drafting note to Section 8 to provide state statutory citations for 15 topic areas that some states might want to consider when developing their state legislation regulating PBMs. He said the 15 topic areas are those areas where the Subgroup found, at this time, a lack of national consensus to include in the proposed PBM model. He said Section 9 and Section 10 provide, respectively, for the severability of the model act’s provisions and an effective date.

Commissioner Conway said as discussed during the Task Force’s Oct. 23 meeting, he does not intend for the Task Force to consider adoption of the proposed PBM model. He said he would like the Task Force to expose the draft for an additional 30-day public comment period.

Mr. Keen made a motion, seconded by Commissioner Clark, to adopt the Subgroup’s report, including its Oct. 29 (Attachment Three), Oct. 22 (Attachment Four), Oct. 8 (Attachment Five), Oct. 1 (Attachment Six), Sept. 24 (Attachment Seven) and Sept. 14 (Attachment Eight) minutes. The report does not include adoption of the proposed PBM model. The motion passed unanimously.

Commissioner Schmidt made motion, seconded by Commissioner Clark, to expose the proposed PBM model (Attachment Three-A) for an additional 30-day public comment period. The motion passed unanimously.

4. Heard a Presentation “Protect Consumers from Individual Health Insurance Marketing and Sales Abuses”

Harry Ting (Healthcare Consumer Advocate) presented on protecting consumers from individual health insurance marketing and sales abuses. He said the problem of deceptive sales of non-federal Affordable Care Act (ACA) plans is well established. He said these practices have been extensively documented by health policy researchers and some state and federal policymakers. He also said numerous stories about individual cases of such abuses have been chronicled in the news media. He listed the states that have taken action to address the issue.

Mr. Ting discussed how these abusive sales and marketing practices have caused serious harm to consumers, including thousands of dollars in uncovered medical bills, unwarranted recission of policies for pre-existing conditions, and financial ruin. He said marketing and sales abuses involving non-ACA plans is an urgent issue because the number of people enrolling in these low-cost plans is significant. The U.S. House of Representatives (House) Committee on Energy & Commerce estimated that 600,000 consumers enrolled in short-term, limited duration (STLD) insurance plans in 2019. Mr. Ting said the federal Centers for Medicare & Medicaid Service (CMS) estimates that total enrollment in these plans will reach 1.9 million in 2022. He said Covered CA, the California health insurance exchange, estimates that in 2019, 100,000 consumers were enrolled in health care sharing ministries (HCSMs) in California and 1,000,000 were enrolled nationally.

Mr. Ting said the purpose of his presentation is to highlight some of these deceptive marketing and sales abuses that he has encountered during his secret shopping experience and the steps that the states and the NAIC should take to address them. He detailed his secret shopper’s demographic characteristics—30-year old, out-of-work, $30,000 – $35,000 annual income, healthy or a diabetic—and his search online for “health insurance” in six states. He discussed the results of the search, noting that fixed indemnity and HCSM plans were the most recommended plans, more than STLD insurance plans. He also discussed the “sellers” of these plans, explaining that most would not give them their names, and of the 11 who did give their names, one had her license revoked in 1981 and another voluntarily terminated their license in 2009.

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Mr. Ting also highlighted the misrepresentation used by some sellers, such as: 1) the deceptive use of existing insurer logos or names; 2) misleading examples to give the illusion of comprehensive benefits; and 3) portraying HCSM plans as excellent “insurance.” He also said some sellers resisted providing plan documentation that would explain plan benefits and limitations. He also described high pressure sales tactics.

Mr. Ting said the states and the NAIC could address these problems in several ways, including enhancing transparency by: 1) requiring the official name of the insurer and its NAIC code on all sales and policy literature; 2) mandating statements of benefits and coverage just like ACA plans are required to provide; and 3) mandating a standardized chart summarizing other key policy provisions. He suggested that the NAIC consider including his suggestions in the revisions to the Model Regulation to Implement the Accident and Sickness Insurance Minimum Standards Model Act (#171), particularly for fixed indemnity, HCSM plans. He said STLD insurance plans should also be subject to similar requirements. He said all these types of plans should be subject to the same requirements whether they are sold individually or through an association.

Mr. Ting also suggested that the states and the NAIC require all marketing and plan materials to advise consumers that they may be eligible for financial assistance if they buy an ACA plan or qualify for Medicaid. In addition, consumers should be provided with information on how to contact navigators or enrollment assistance in their state to be better able to explore their options for health insurance coverage. Mr. Ting also provided recommendations for strengthening pre-existing condition protections.

Mr. Ting discussed holding insurers independently responsible for violation of state regulations by sellers of their plans. He said general agents and independent agencies should also be held independently responsible for their producers’ violations of state regulations. He also discussed how surveying consumers enrolled in these non-ACA plans could identify and highlight marketing and sales abuses.

Mr. Ting acknowledged the challenges the states and the NAIC might have in implementing his suggestions, but he noted the urgency in addressing these problems because consumers are being harmed and the states can do more than what they are doing currently.


Marc Machiz (Justican Mediation LLC) discussed the recent decision in Data Marketing Partnership, et al. vs. U.S. Department of Labor, et al. He said this case involves a scheme to exploit the provisions of the Employee Retirement Income Security Act of 1974 (ERISA), which exempts bona fide self-insured employee benefit plans from insurance regulation. He noted that there is a long history of attempts to evade insurance regulation by fraudulently claiming this exemption. He explained that in this latest attempt, Data Marketing Partnership (DMP) and other affiliated enterprises sell health coverage to the general public by inviting customers to become “limited partners,” who then become eligible to pay for membership in the partnership’s “benefit plan.” Although DMP characterizes its customers as “working owners,” its limited partnership gives them no meaningful ownership stake in the business and the only “work” they perform is to install a tracking app on their phones, which allows the partnership to sell their personal data to third parties.

Mr. Machiz said the U.S. Department of Labor (DOL) recognized in Advisory Opinion 2020-01A that the DMP is not a bona fide ERISA plan, but simply a scheme to try to avoid regulatory oversight of “the commercial sale of insurance outside the context of employment-based relationships.” He said the DMP and its parent company brought suit to challenge the opinion in the U.S. District Court for the Northern District of Texas, which ruled Sept. 28 that the DOL’s opinion was arbitrary and capricious and it had no authority to consider whether the customers’ purported ownership interests are “nominal” or “material,” whether the customers engaged in “meaningful” work or they had any realistic expectation of earning income from that work. The court ruled that it did not matter whether DMP is a “legitimate business enterprise” at all.

Mr. Machiz said at this point, the DOL has not decided whether it will appeal the decision. He noted how problematic this case could be for state insurance regulators, particularly with the possibility of other entities looking at forming similar schemes and the possibility of insolvencies and the non-payment of claims involving such schemes, similar to what has happened in the past. He suggested that the states consider using their own authority to investigate and stop these schemes in state court because the District Court’s ruling does not bind the states. He noted Washington’s current investigation into this arrangement.

Commissioner Conway said the NAIC is sending a letter to the DOL, urging it to appeal the decision. He asked about the possibility of removing a state court suit involving the DMP to the federal court to ultimately create a circuit court split on the federal level. Mr. Machiz suggested that the states keep their suits in state court because the state will most likely get a more sympathetic hearing on the ERISA preemption issue than in federal court. He also noted that the DMP decision also represents an end run around the ACA individual market requirements.
6. Discussed Possible Next Steps Regarding HCSMs

Commissioner Conway said during the Task Force’s Oct. 23 meeting, he had agreed to revisit the issue of HCSMs. He said Commissioner Mulready had asked if the Task Force plans to take any additional action related to HCSMs. He said during the Task Force’s meeting at the Summer National Meeting, the Task Force heard presentations highlighting the pros and cons of HCSMs.

Commissioner Mulready said he believes that during an NAIC meeting earlier this year, there was some discussion during the Health Insurance and Managed Care (B) Committee breakout session of forming a new NAIC group under the Task Force on HCSMs. He said he would be interested to know if Task Force members wanted to move forward with this idea or continue to hold presentations on HCSMs. Commissioner Conway asked for comments from Task Force members. There were no comments.

Commissioner Conway said he recognizes that there are many Task Force members in the meeting who have not had the opportunity to think in depth on this issue. He suggested that the Task Force defer the discussion of its potential next steps at this time and revisit it in the future. There was no objection to his suggestion.

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)
ACCIDENT AND SICKNESS INSURANCE MINIMUM STANDARDS (B) SUBGROUP

Summary Report

The Accident and Sickness Insurance Minimum Standards (B) Subgroup of the Regulatory Framework (B) Task Force has not met since Dec. 16, 2019 due to the COVID-19 health emergency and the loss of one of its co-chairs, the Subgroup has not met since December 2019. A new Subgroup co-chair was recently appointed. It is anticipated the Subgroup will begin meeting sometime in April following the Spring National Meeting to complete its discussion of the comments received on Sections 1-5 of the Model Regulation to Implement the Accident and Sickness Insurance Minimum Standards Model Act (#171) and begin discussion of the comments received on Sections 6 and 7 of Model #171.
EMPLOYEE RETIREMENT INCOME SECURITY ACT (ERISA) (B) WORKING GROUP

Summary Report

The Employee Retirement Income Security Act (ERISA) (B) Working Group has met in open session since 2020. The Working Group will most likely next meet sometime following the Spring National Meeting to discuss any updates regarding association health plans (AHPs), including the status of the appeal in State of New York et al. v. U.S. Department of Labor et al. The Working Group also could discuss the U.S. Supreme Court’s decision in Rutledge vs. the Pharmaceutical Care Management Association (PCMA) with respect to any ERISA preemption issues. It then 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
March 10, 2021 / January 28, 2021

Meeting Summary Report

The Mental Health Parity and Addiction Equity Act (MHPAEA) (B) Working Group met March 10, 2021, in lieu of meeting at the Spring National Meeting 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 Jan. 28, 2021, to hear from stakeholders—consumers, providers and plans—on their experiences with the implementation of and compliance with the MHPAEA’s mental health parity requirements.
The MHPAEA (B) Working Group of the Regulatory Framework (B) Task Force met Jan. 28, 2021. The following Working Group members participated: Katie Dzurec, Chair, Shannen Logue and Frank Callihan (PA); Jane Beyer, Vice Chair, Jeanette Plitt, Paul Dubois and John Haworth (WA); Jimmy Harris, Donna Lambert, Crystal Phelps and Chantel Allbritton (AR); Mary Boatright, Jeanette Henagan, Erin Klug and Vanessa Darrah (AZ); Pam O’Connell, Jessica Ryan, Doris Walker, Sheirin Ghoddoucy and Christopher Citko (CA); Cara Cheevers, Kate Harris and Damion Hughes (CO); Kurt Swan, Courtney Miner, Paul Lombardo and Robert Chester (CT); Howard Liebers and Mary Beth Senkewicz (DC); Sarah Crittenden (GA); Cynthia Banks Radke, Sonya Sellmeyer, Angela Burke Boston, Lindsay Bates, Andria Seip and Jan Jones (IA); Ryan Gillespie, Sara Stanberry, Kate Morthland and Erica Weyhenmeyer (IL); Shannon Lloyd, Chris Hollenbeck, Craig VanAalst, Brenda Johnson, Barbara Torkelson, Tate Flott, Julie Holmes and Mark McClaffin (KS); Erica Bailey (MD); Peter Brickwede and Andrew Kleindendorst (MN); Jeanne Keller (MT); Ted Hamby, Rosemary Gillespie, Shane Quinlan, Kathy Shortt, Tracy Biehn and Cheryl Bivens (NC); Sara Gerving, Colton Starseth, Chystal Bartuska and Ross Hartley (ND); Ingrid Marsh, Michelle Heaton, and Tyler Brannen (NH); Ralph Boeckman, Gale Simon, Erin Porter and Channell McDevitt (NJ); Sherri Mortensen-Brown, Viara Ianakieva, Diane Bilodeau, Julie Weinberg and Sarah Grisham (NM); Laura Miller, Guy Self, Kyla Dembowski, Todd Oberholtzer, Molly Mottram and Marjorie Ellis (OH); Alyssa Metivier, Victor Woods, Emily Maranjian and John Garrett (RI); Kendall Buchanan and Michael Bailes (SC); Jill Kruger and Lisa Harmon (SD); Rachel Bowden and Angela Melina Raab (TX); Tanji J. Northrup, Carrie Backus, Elizabeth Clasen, and Jaakob Sundberg (UT); Brant Lyons, Melissa Gerachis, Heather Webb, Ansley Fitzpatrick, Bryan Wachter, Jarod Mentzer, Julie Fairbanks and Tiffany Toney (VA); Barbara Belling, Jody Ullman, Diane Dambach and Mark Prodoehl (WI); Joylynn Fix (WV); and Denise Burke, Tina Howard and Mavis Earnshaw (WY).

1. Heard a Presentation on Consumer Experiences with MHP

Andrew Sperling (National Alliance on Mental Illness—NAMI) provided an overview of federal mental health parity (MHP) legislation and its interaction with state laws. He characterized the law as a success for consumers, but he said challenges remain, including enforcement and a lack of clarity on non-quantitative treatment limits (NQTLs). He said state insurance regulators should ensure compliance when behavioral health benefits are carved-out, tackle the difficulties of network adequacy in mental health, and work toward a recognized accreditation process, such as through URAC. He said the prospective medical management of inpatient hospitalization remains a big challenge and a difference from the way medical/surgical (MS) benefits are treated.

Ms. Beyer asked whether there is concern with insurers approving a lower level of care than requested by a provider. Mr. Sperling said plans insist on a lower level of care, even calling the provider every day to ask for discharge from an inpatient setting. Ms. Beyer asked about experiences consumers have in appealing determinations that a lower level of care is all that will be paid. Mr. Sperling said it is a large challenge for families, especially when the patient is in crisis. Ms. Dzurec asked whether there are different definitions of emergency services for psychiatric care versus MS services. Mr. Sperling said there are different legal standards, particularly for involuntary confinement. He said these legal considerations complicate health plan determinations because these are legal proceedings where law enforcement may be involved. Ms. Harris asked whether there is an opportunity to use criteria from the American Society of Addiction Medicine (ASAM) to guide coverage decisions. Mr. Sperling said this is a hot topic and the challenge is that treatment guidelines are different for each condition.

2. Heard a Presentation on Provider Experiences with MHP

Tim Clement (American Psychiatric Association—APA) described health care providers’ experiences with MHP. He said utilization reviews for behavioral health often involve second-level review and peer-to-peer reviews in which the reviewer strongly encourages the provider to seek a lower level of care. He said smaller practices are at a disadvantage in negotiating with insurers, regardless of the scarcity of providers in a market. He outlined a number of prescription drug and formulary issues providers face. He urged state insurance regulators to look to medical experts in their states as well as state insurance regulators in other states who are performing parity market conduct exams.
3. **Heard a Presentation on Health Plan Experiences with MHP**

Lisa Campbell and Ryan Temme (Groom Law Group) presented on health plans’ perspectives on MHP. Ms. Campbell noted that their remarks represent the views of America’s Health Insurance Plans (AHIP), the Association for Behavioral Health and Wellness (ABHW), and the Blue Cross Blue Shield Association (BCBSA). Ms. Campbell described federal laws, noting the complexity of the tests for parity compliance. She referenced existing federal compliance tools. Mr. Temme emphasized the need for plans to better understand what would be considered compliant, particularly with regard to NQTLs. He described three levels of complexity with parity requirements: 1) a wide variety of covered plans; 2) the variety of approaches that are permissible; and 3) the different levels of analysis that a state insurance regulator could request. He said workforce shortages and the reluctance of providers to join networks contribute to the way plans offer and pay for mental health benefits and add to the complexity of compliance analysis. He said the rule is focused on the process, so different outcomes are not determinative of compliance. Ms. Campbell said federal guidance under recent legislation to require comparative analyses will provide a uniform standard for plans to report on their NQTLs.

Pamela Greenberg (ABHW) said her organization’s main goal is to have a uniform implementation process and certainty for plans regarding what is compliant and non-compliant. Randi Chapman (BCBSA) said her organization seeks clarity and wants the new federal law to lead to consistent and transparent guidance. She said the new law provides an opportunity for a uniform approach. Miranda Motter (AHIP) recommended that the Working Group work with stakeholders to implement the new federal law, and she said work outside the framework of the new law could add confusion.

Ms. Beyer asked what role issuers have in making it easier for behavioral health providers to be part of plan networks. Ms. Greenberg said some providers do not have the means to offer telehealth and plans have helped there. She said plans have worked to reduce the administrative burden and provider partnerships can be more complex than working in a solo practice without taking insurance. Ms. Motter said another potential consideration is providers operating at the top of their licenses. Ms. Greenberg said collaborative care models are a good example of psychiatrists practicing at the top of their licenses, and it can help for plans to encourage and reimburse such models.

Ms. Dzurec asked about using provider ratios in measuring network adequacy. Mr. Clement said whether providers are taking new patients is an important consideration in addition to provider ratio. Ms. Greenberg said the variety of provider types in behavioral health must also be considered. Ms. Motter said telehealth should also be considered with regard to satisfying provider ratios.

Ms. Dzurec asked about federal guidelines for comparative analyses and how states can ask plans for them. Amber Rivers (U.S. Department of Labor—DOL) said it is a transitional time and guidance will come later. She added that much of the language in the new law is borrowed from existing statutes and regulations, so the concepts are not new. Mary Nugent (Center for Consumer Information and Insurance Oversight—CCIIO) said guidance has not yet been released, but there is nothing in federal law that prevents state insurance regulators from requesting analyses from state-regulated plans.

Having no further business, the MHPAEA (B) Working Group adjourned.
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 may resume meeting again 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.
Agenda Item #3

Hear an Update on the Center on Health Insurance Reforms’ (CHIR’s) Work Related to the Federal Affordable Care Act (ACA)
—Justin Giovannelli (CHIR, Georgetown University Health Policy Institute)
Update on Georgetown CHIR’s Recent and Forthcoming Work

National Association of Insurance Commissioners Regulatory Framework (B) Task Force
March 25, 2021

Justin Giovannelli, J.D., M.P.P.
Associate Research Professor
Federal Developments Affecting State Insurance Markets

• The American Rescue Plan Act and Extended Marketplace Enrollment Periods
  – Impacts on access, affordability
  – Implementation challenges

• Implementation of the No Surprises Act

• Fixing the “family glitch”
State Policy and the Individual Market

• Section 1332 waivers
  – Reinsurance
  – Other options in light of ARP, administration change?

• The market for non-comprehensive coverage

• Tracking state regulatory approaches to:
  – Individual market affordability; pandemic response; surprise billing
On the Horizon

- Network adequacy
  - State and federal options

- Standardized health plans
  - State and federal options

- More on non-comprehensive coverage arrangements
  - Short-term products
  - Healthcare sharing ministries
Thank you

Justin Giovannelli
Associate Research Professor
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Justin.Giovannelli@georgetown.edu
Agenda Item #4

Hear Presentation on Federal No Surprises Act: Impact on the States
—Jack Hoadley and Kevin Lucia (Georgetown University Health Policy Institute)
The No Surprises Act: Implications for States

NAIC Regulatory Framework Task Force

March 25, 2021
Jack Hoadley and Kevin Lucia
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
Surprise Medical Bills

- Result from interactions with providers that patients *reasonably assumed would be in network but were not*, or when patients have *no real choice* of provider.

<table>
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<tr>
<th>Where they come from</th>
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| Emergency situations                                     | • ED physicians OON at in-network facility  
• Closest emergency facility is OON                           |
| Nonemergency care at an in-network facility              | • Surgery at network facility with network surgeon may include an OON anesthesiologist, radiologist, pathologist, assistant surgeon, or other specialist  
• OON hospitalist provides care at network facility     |
| Ambulance services                                       | • Ground or air ambulance dispatched is OON                                                                                     |
No Surprises Act

- 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
- New protections for states that don’t have their own balance billing laws and for the nearly 135 million in self-insured plans beyond the reach of state law.

- The analysis presented is based on the best reading by the Georgetown team. The federal rulemaking process may reach different conclusions.
Scope of Protections

- Which plans are covered by federal law?
  - Fully insured plans
  - Self-funded plans
  - Grandfathered plans
  - *Excludes* short-term plans and excepted benefit (dental, vision)

- Where do protections apply?
  - Non-emergency care at in-network facilities provided by out-of-network clinicians
  - Emergency care provided in in-network or out-of-network facilities
  - Post-stabilization services until the patient can travel using nonmedical or non-emergency medical transportation
  - Air ambulance services
  - *Excludes* ground ambulances

*Georgetown University Health Policy Institute*

CENTER ON HEALTH INSURANCE REFORMS
Nature of Protections

• How are patients protected?
  • Patients responsible for in-network cost sharing only
  • Cost sharing payments count toward the in-network deductible and out-of-pocket limit
  • Coinsurance is based on the “recognized amount,” generally the median in-network rate or the amount determined under state law
  • Providers are barred from sending or collecting a bill for amounts other than in-network cost sharing
Determining Payment for Out-of-Network Care

• Payment for out-of-network care is determined:
  • 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.
  • 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.
  • For other states or for plans not regulated by the state (self-funded plans), the federal method applies.
  • For services not regulated by the states, such as air ambulances, the federal method applies.
Federal Method for Determining Payment for Out-of-Network Care

- Health plan or insurer can, within certain timeframes, negotiate the payment amount with the provider or facility
- Failing that, either party can request arbitration through an independent dispute resolution (IDR) entity
- IDR features include:
  - Multiple items and services may be batched for a single arbitration
  - Parties submit amounts; arbitrator must select one
  - Decision is binding; losing party pays the cost of arbitration
  - Key factor for arbitrators: insurer’s median in-network rate but not public-sector rates
  - Other factors: case and provider characteristics, prior contracted rate
Waiving Protections

• Protections do not apply when patient knowingly and voluntarily agrees to receive care from certain out-of-network providers

• Providers can request that a patient sign a consent to receive non-emergency care from an out-of-network provider or facility

• Protections cannot be waived when:
  • There is no in-network provider available
  • For urgent or unforeseen care
  • Services are delivered by providers in designated specialties, (e.g., anesthesiology, pathology, radiology, neonatology), hospitalists, intensivists, assistant surgeons, and others that may be designated by Secretary through rulemaking
Emergency Transport

• Air ambulance
  • Consumer protections match those for other emergency services
  • Federal IDR system with similar factors, including in-network rate
  • Requirement for cost reporting and secretarial report
  • Advisory committee on air ambulance quality and patient safety

• Ground ambulance
  • No protections established in the No Surprises Act
  • Advisory Committee on Ground Ambulances and Patient Billing will make recommendations for states and the Congress
  • Law calls for committee to be formed 90 days after enactment
  • Committee to report 180 days after first meeting
Enforcement on Insurers

• State departments of insurance are the primary enforcers of provisions that apply to insurers and fully insured group health plans
• Federal government enforces in states that fail to substantially enforce the law and for self-funded group health plans
Enforcement on Providers, Facilities

- States may enforce provisions on providers (including air ambulances) but federal government will do so where a state fails to substantially enforce the law
  - Law is silent on which state agency is responsible for enforcing provider provisions – unless addressed through rulemaking
- States have taken various approaches:
  - Vest enforcement authority for providers in the 1) insurance department 2) health department 3) medical licensing entity, 4) consumer protection agency or 5) attorney general
  - Some use “blended” approach to provider enforcement: allowing insurance department or provider licensing entity to report patterns of unresolved or intentional violations to another entity
Reporting

- Data Reporting
  - Extensive reporting requirements for the outcomes of IDR, including the final amounts as a percentage of the median in-network rate (but not on negotiated settlements)

- Studies to Monitor Implementation
  - Effect on health care costs
  - Effect on provider consolidation
  - Effect on provider networks
Additional Provisions

• Continuity of Care: When provider contract ends, some patients can maintain access to the provider with in-network cost sharing.

• Provider Directories: Applies requirements to providers and health plans to keep provider directories current and accurate.

• Advanced Explanation of Benefits: Providers and facilities are required under law to provide good-faith cost estimate to insured and uninsured.

• Dispute Resolution for Uninsured: New process to contest charges that “substantially exceed” the good-faith estimate.

• All Payer Claims Database Funding: Grants to states and new standardized reporting form for data from group health plans.
Communications and Education

• How will consumers learn about their rights under both federal and state laws?
• How will providers and insurers learn about their roles under federal and state laws?
• Challenges for understanding and using the laws
  • Which cases are in state versus federal jurisdictions?
  • How do parties determine which laws apply?
  • What should consumers do if they receive balance bills?
  • Where do parties direct their questions?
• What responsibilities do states have to educate all interested parties?
Considerations for States with Balance Billing Laws

- In general, state laws can be more consumer protective, as long as they don’t “prevent the application of federal law.”
- Example provisions where state laws may differ
  - Waiver of protections by the consumer
  - Scope of providers (out-of-network facilities, certain specialties)
  - Protection for post-stabilization services
- How will it be determined where federal law prevails?
- Law explicitly defers to states on provider directory requirements
- Federal law has no provisions applying protections in certain areas (e.g., ground ambulances, short-term plans), leaving states the opportunity to regulate
Considerations for States with a Method to Determine Payments

• In general, states using either a payment standard, arbitration, or a hybrid combining both will use their method for services regulated under state law
• Will federal rules have any standard for what counts for a deferral?
• What happens when a case is mixed, e.g., state law applies to the physician service, but the state law does not apply to the facility?
• What happens when a person residing in and insured in one state receives services out of network in another state?
Next Steps for New Law

- Secretaries of HHS, Labor and Treasury must draft regulations to implement multiple provisions, including:
  - Creation and maintenance of the IDR system
  - Criteria for batching multiple claims for submission to IDR
  - Criteria for the certification of IDR entities
  - Methodology for calculating median in-network rates (including NAIC role on geographic regions for these determinations)
  - Complaint process for patients

- Timeline for Rulemaking:
  - Two provisions where rulemaking must be done by 7/1/21: consent forms and methodology for in-network rate
  - Otherwise, no deadlines in law
Opportunities for States to Engage

- States with balance billing laws may want to ensure federal regulators understand how those laws operate to mitigate disruption or confusion for regulated entities and consumers.
- States may also want to weigh in on state law provisions that may be more protective of consumers.
- Where state laws are less protective, should they be changed to come into alignment?
- State experiences may be instructive to federal rulemaking.
- Do states need authorization to enforce this federal law?
Resources

Jack Hoadley, Research Professor Emeritus, jfh7@georgetown.edu
Kevin Lucia, Research Professor, kwl@georgetown.edu
Georgetown University Center on Health Insurance Reforms

Website: https://surprisemedicalbills.chir.georgetown.edu/
Interactive map:
Health Affairs blog:
Commonwealth Fund blog with link to detailed summary:
https://www.commonwealthfund.org/blog/2020/surprise-billing-protections-cusp-becoming-law
Agenda Item #5

Hear a Discussion of the Decision in *Rutledge vs. Pharmaceutical Care Management Association (PCMA)*—Katie Keith (Out2Enroll)
Rutledge v. PCMA: An Overview

Regulatory Framework (B) Task Force

Katie Keith, JD, MPH
### Brief Background

#### Lower Court History
Arkansas adopted Act 900 (2015) to require PBMs to reimburse pharmacies at a price equal to/higher than what the pharmacy paid to a wholesaler
- Tethers PBM reimbursement rates to pharmacy acquisition costs
- Authorizes administrative appeals procedures for pharmacies to challenge reimbursement rates
- Allows pharmacies to decline to sell a drug if PBM reimbursement is below acquisition costs

PCMA sued, arguing that Act 900 is preempted under ERISA
- District court and Eighth Circuit agreed (2018) based on analysis of similar statute from Iowa

#### Supreme Court History
- Scheduled for Court’s 2019 term but delayed to 2020 term due to COVID-19
- Oral argument on Oct. 6, 2020, decision issued on Dec. 10, 2020
- Unanimous decision by Justice Sotomayor (8-0), concurrence by Justice Thomas → Act 900 is not preempted by ERISA
ERISA Preemption Standard

29 U.S.C. § 1144(a): ERISA “shall supersede any and all State laws insofar as they may now or hereafter relate to any employee benefit plan”

Prior case law:
- State law relates to an ERISA plan if it has a connection with or reference to such plan
- State law is preempted if it “governs a central matter of plan administration or interferes with nationally uniform plan administration” (e.g., laws that require providers to structure benefit plans in particular ways or mandate specific rules for beneficiary status)
- Not all state laws that affect ERISA plans or result in some disuniformity are preempted → especially if the law “merely affects costs” (Travelers, 1995)
Supreme Court’s Analysis

Act 900 is not preempted by ERISA

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

- “ERISA does not pre-empt 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 does not “refer to” ERISA → it does not apply “immediately and exclusively” to ERISA plans and its application to ERISA plans is not “essential to the law’s operation”

- Act 900 does not directly regulate health plans at all and applies to PBMs whether they act pursuant to an ERISA plan or not
Rejected PCMA’s arguments that Act 900 has an impermissible connection with ERISA plans

PCMA: Act 900’s enforcement mechanisms directly affect central matters of plan administration and interfere with nationally uniform plan administration

SCOTUS: these mechanisms do not require plan administrators to structure their benefit plans in a particular way

- Act 900 “simply establishes a floor for the cost of benefits that plans choose to provide”
- ERISA does not preempt state laws that merely increase costs even if plans decide to limit benefits or charge higher rates as a result
- PCMA’s position would preempt any state laws that could affect the price or provision of benefits
Justice Thomas: urges reconsideration of the jurisprudence on ERISA preemption, suggests that the preemption provision is not sweeping and a simpler test would suffice → ERISA does not govern any same matter as Act 900 so Act 900 stands

State activity on PBM regulation may have helped bolster the Court’s conclusion: “[I]t should come as no surprise that the Supreme Court has no interest in stepping in to protect a market that almost all of the states regard as functioning so poorly as to warrant legislative intervention. If Congress disagrees, it certainly could amend ERISA to compel a different arrangement.” (SCOTUSblog)

*Rutledge* likely expands options for states in the direct regulation of health care costs and could narrow the range of state regulations preempted by ERISA (Health Affairs)
Thank you!

Katie Keith, JD, MPH
katie.keith@georgetown.edu
More resources available at: healthaffairs.org/blog
Agenda Item #6

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