

## **REGULATORY FRAMEWORK (B) TASK FORCE**

Regulatory Framework (B) Task Force Nov. 19, 2020, Minutes

Regulatory Framework (B) Task Force Oct. 23, 2020, Minutes (Attachment One)

Regulatory Framework (B) Task Force 2021 Proposed Charges (Attachment One-A)

Regulatory Framework (B) Task Force Sept. 24, 2020, Minutes (Attachment Two)

Pharmacy Benefit Manager Regulatory Issues (B) Subgroup Oct. 29, 2020, Minutes (Attachment Three)

Pharmacy Benefit Manager Model Draft Dated Oct. 29, 2020 (Attachment Three-A)

Pharmacy Benefit Manager Regulatory Issues (B) Subgroup Oct. 22, 2020, Minutes (Attachment Four)

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Pharmacy Benefit Manager Regulatory Issues (B) Subgroup Sept. 14, 2020, Minutes (Attachment Eight)

## 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. Ramage, 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 Trexler 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

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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 rescission 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.

### 5. Heard a Discussion of the Decision *Data Marketing Partnership, et al. vs. U.S. Department of Labor, et al.*

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.

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### **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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Draft: 11/4/20

Regulatory Framework (B) Task Force  
Virtual Meeting  
October 23, 2020

The Regulatory Framework (B) Task Force met Oct. 23, 2020. The following Task Force members participated: Michael Conway, Chair (CO); Bruce R. Ramge, Vice Chair (NE); Lori K. Wing-Heier represented by Sarah Bailey (AK); Jim L. Ridling represented by Anthony Williams, William Rodgers and Yada Horace (AL); Alan McClain (AR); Elizabeth Perri (AS); Ricardo Lara represented by Bruce Hinze, Tyler McKinney and Sheirin Ghoddoucy (CA); David Altmaier (FL); Doug Ommen represented by Andria Seip (IA); Dean L. Cameron represented by Weston Trexler and Kathy McGill (ID); Robert H. Muriel represented by Eric Anderson (IL); Vicki Schmidt (KS); Sharon P. Clark represented by DJ Wasson (KY); Gary Anderson represented by Kevin Beagan (MA); Eric A. Cioppa represented by Robert Wake (ME); Grace Arnold represented by Peter Brickwedde and Candace Gergen (MN); Chlora Lindley-Myers (MO); Mike Causey represented by Della Shepherd (NC); Jon Godfread represented by Chrystal Bartuska and Johnny Palsgraaf (ND); Chris Nicolopoulos represented by Maureen Belanger (NH); Glen Mulready represented by Andrew Schallhorn (OK); Andrew R. Stolfi represented by TK Keen and Gayle L. Woods (OR); Jessica K. Altman (PA); Raymond G. Farmer represented by Kendall Buchanan (SC); Larry D. Deiter (SD); Kent Sullivan represented by Richard Lunsford, Rachel Bowden and Doug Danzeiser (TX); Tanji J. Northrup (UT); Scott A. White represented by Jackie Myers (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. Disbanded the HMO Issues (B) Subgroup

Commissioner Conway said the Health Maintenance Organization (HMO) Issues (B) Subgroup has completed its work with the Task Force's Sept. 24 adoption of the revisions to the *Health Maintenance Organization Model Act* (#430). These revisions addressed the redundancies and inconsistencies in its provisions with the 2017 revisions to the *Health and Life Insurance Guaranty Association Model Act* (#520). Given this, the Subgroup can be disbanded.

Commissioner Altman made a motion, seconded by Director Ramge, to disband the HMO Issues (B) Subgroup. The motion passed unanimously.

2. Adopted its 2021 Proposed Charges

Commissioner Conway said that prior to the meeting, NAIC staff distributed the Task Force's 2021 proposed charges. He explained that the proposed charges generally are unchanged from the Task Force's 2020 charges. He said the HMO Issues (B) Subgroup's 2020 charges were deleted because it has completed its work and has been disbanded. He explained that the Mental Health Parity and Addition Equity Act (MHPAEA) (B) Subgroup's charges are revised to reflect the Working Group's current and ongoing work with appropriate Market Regulation and Consumer Affairs (D) Committee groups.

Mr. Keen made a motion, seconded by Commissioner Altman, to adopt the Task Force's 2021 proposed charges (Attachment One-A). The motion passed unanimously.

3. Received an Update on the Pharmacy Benefit Manager Regulatory Issues (B) Subgroup's Work

Mr. Keen discussed the Subgroup's drafting process to date. He said that 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 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 that at the conclusion of these meetings, the Subgroup decided it had obtained sufficient information to move forward with its charge. The Subgroup then established an ad hoc drafting group to develop an initial draft based on the Subgroup's discussions. He said that 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 exposed the draft for a public comment period ending Sept. 1.

Mr. Keen said the Subgroup received 19 comment letters from various stakeholders. He said the Subgroup discussed the comments received during almost weekly meetings beginning in late September through October. He said that based on this discussion, the Subgroup revised the draft and anticipates adopting it during its next meeting Oct. 29. Once adopted, he anticipates forwarding it to the Task Force for its consideration during the Task Force's Nov. 19 meeting.

Mr. Keen explained that the draft 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. He encouraged the Subgroup obtain a greater understanding of the impacts of PBM regulation on prescription drug pricing before committing significant state resources to such regulation. Given this lack of consensus, Mr. Keen said the Subgroup's draft is a straight-forward PBM licensing model that includes a gag clause provision and an information-sharing provision. He said the draft also includes a drafting note outlining 15 separate PBM-related issues, such as prohibiting clawbacks, prohibiting spread-pricing, and PBM network adequacy and transparency. Finally, the draft includes state statutory citations to provisions in current state laws that those states wanting to include such provisions as part of their adoption of the proposed PBM model can use.

Commissioner Conway said that before the Task Force considers adoption of the Subgroup's draft, the Task Force will expose it for a 30-day public comment period. He said that in discussing the Subgroup's draft with Mr. Keen, it is his understanding that the *Rutledge v. Pharmaceutical Care Management Association* case, which is currently before the U.S. Supreme Court, would not affect the proposed PBM model because the draft is focused on PBM licensing and not any of the provisions at issue in the Rutledge case. Mr. Keen agreed.

Commissioner Conway asked if anyone had any questions. There were no questions.

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

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Draft: 10/12/20

*Adopted by the Health Insurance and Managed Care (B) Committee – Nov. 2, 2020*

*Adopted by the Regulatory Framework (B) Task Force – Oct. 23, 2020*

## 2021 PROPOSED CHARGES

### REGULATORY FRAMEWORK (B) TASK FORCE

The mission of the Regulatory Framework (B) Task Force is to: 1) develop NAIC model acts and regulations for state health care initiatives; and 2) consider policy issues affecting state health insurance regulation.

#### Ongoing Support of NAIC Programs, Products and Services

1. The **Regulatory Framework (B) Task Force** will:
  - A. Coordinate and develop the provision of technical assistance to the states regarding state-level implementation issues raised by federal health legislation and regulations.
  - B. Review managed health care reforms, their delivery systems occurring in the marketplace and other forms of health care delivery. Recommend appropriate revisions to regulatory jurisdiction, authority and structures.
  - C. Consider the development of new NAIC model laws and regulations and the revision of existing NAIC model laws and regulations, including those affected by federal legislation and final federal regulations promulgated pursuant to such legislation.
  - D. Continue to review NAIC models recommended for revision by the former Affordable Care Act (ACA) Model Review (B) Working Group and, as appropriate, appoint a working group or subgroup to revise the NAIC model(s) prioritized for revision in 2021.
  - E. At the direction of the Health Insurance and Managed Care (B) Committee, through the work of the Employee Retirement Income Security Act (ERISA) (B) Working Group, monitor, analyze and report developments related to association health plans (AHPs).
  - F. Monitor, analyze and report, as necessary, developments related to short-term, limited-duration (STLD) coverage.
2. The **Accident and Sickness Insurance Minimum Standards (B) Subgroup** will:
  - A. Review and consider revisions to the *Model Regulation to Implement the Accident and Sickness Insurance Minimum Standards Model Act* (#171).
3. The **ERISA (B) Working Group** will:
  - A. Monitor, report and analyze developments related to the federal ERISA, and make recommendations regarding NAIC strategy and policy with respect to those developments.
  - B. Monitor, facilitate and coordinate with the states and the U.S. Department of Labor (DOL) related to sham health plans.
  - C. Monitor, facilitate and coordinate with the states and the DOL regarding compliance and enforcement efforts regarding the ACA that relate to ERISA.
  - D. Review the *Health and Welfare Plans Under the Employee Retirement Income Security Act: Guidelines for State and Federal Regulation* (ERISA Handbook) and modify it, as necessary, to reflect developments related to ERISA. Report annually.
4. The **Mental Health Parity and Addiction Equity Act (MHPAEA) (B) Working Group** will:
  - A. Monitor, report and analyze developments related to the federal Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA), and make recommendations regarding NAIC strategy and policy with respect to those developments.
  - B. Monitor, facilitate and coordinate best practices with the states, the DOL and the U.S. Department of Health and Human Services (HHS) related to the MHPAEA.
  - C. Monitor, facilitate and coordinate with the states and the DOL regarding compliance and enforcement efforts regarding the ACA that relate to the MHPAEA.
  - D. Provide supplemental resources to support documentation and reporting in the MHPAEA chapter of the NAIC *Market Regulation Handbook*.
  - E. Coordinate with and provide input to Market Regulation and Consumer Affairs (D) Committee groups, as necessary, regarding mental health parity market conduct examinations.



5. The **Pharmacy Benefit Manager Regulatory Issues (B) Subgroup** will:
  - A. Consider developing a new NAIC model to establish a licensing or registration process for pharmacy benefit managers (PBMs). The Subgroup may consider including in the new NAIC model provisions on PBM prescription drug pricing and cost transparency.

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

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Draft: 9/28/20

Regulatory Framework (B) Task Force  
Conference Call  
September 24, 2020

The Regulatory Framework (B) Task Force met via conference call Sept. 24, 2020. The following Task Force members participated: Michael Conway, Chair, represented by Kate Harris (CO); Bruce R. Ramge, Vice Chair (NE); Lori K. Wing-Heier represented by Sarah Bailey (AK); Jim L. Ridling represented by Anthony Williams, William Rodgers and Yada Horace (AL); Alan McClain represented by Mel Anderson (AR); Ricardo Lara represented by Tyler McKinney and Sheirin Ghoddoucy (CA); Karima M. Woods represented by Howard Liebers (DC); David Altmaier represented by Chris Struk (FL); Doug Ommen (IA); Robert H. Muriel represented by Eric Anderson and Sara Stanberry (IL); Vicki Schmidt represented by Julie Holmes and Craig Van Aalst (KS); Sharon P. Clark represented by DJ Wasson (KY); Gary Anderson represented by Kevin Beagan (MA); Eric A. Cioppa represented by Robert Wake (ME); Grace Arnold represented by Sherri Mortensen-Brown and Candace Gergen (MN); Chlora Lindley-Myers (MO); Mike Causey represented by Ted Hamby (NC); Jon Godfread represented by John Arnold, Chrystal Bartuska and Sara Gerving (ND); Chris Nicolopoulos represented by Maureen Belanger (NH); Glen Mulready represented by Ron Kreiter (OK); Jessica K. Altman represented by Katie Dzurec (PA); Raymond G. Farmer represented by Shari Miles (SC); Larry D. Deiter (SD); Kent Sullivan represented by Rachel Bowden (TX); Todd E. Kiser represented by Tanji 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 Joylynn Fix and Tim Sigman (WV).

1. Adopted Revisions to Model #430

Ms. Harris said the main purpose of the Task Force's conference call is to consider adoption of the revisions to the *Health Maintenance Organization Model Act* (#430), as adopted by the Health Maintenance Organization (HMO) Issues (B) Subgroup on July 13. Mr. Beatty said that after the Subgroup was appointed and its charge adopted in 2019, the Subgroup met via conference call throughout 2019 to discuss its approach to completing its charge to revise provisions in Model #430 to address conflicts and redundancies with provisions in the revised *Life and Health Insurance Guaranty Association Model Act* (#520), which added HMOs as members of the guaranty association. He said that during these meetings, the Subgroup identified several provisions in Model #430 to delete to reconcile it with the 2017 revisions to Model #520. Those provisions include Section 14 – Continuation of Benefits, Section 20 – Uncovered Expenditures Deposit and Section 3HH, the definition of “uncovered expenditures.” Mr. Beatty said that for states that do not intend to adopt the revised Model #520, for reference, a new appendix to Model #430 includes these deleted provisions. He said the Subgroup also deleted Section 21 – Open Enrollment and Replacement Coverage in the Event of Insolvency because its provisions are obsolete due to the federal Affordable Care Act (ACA). Mr. Beatty said the Subgroup met July 13 via conference call and during this meeting, the Subgroup unanimously adopted the revisions and agreed to forward the revised model to the Task Force for its consideration.

Ms. Nollette made a motion, seconded by Ms. Northrup, to adopt the Subgroup report and the revisions to Model #430 (*see NAIC Proceedings – Summer 2020, Regulatory Framework (B) Task Force, Attachment Four-B*). The motion passed unanimously.

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

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Draft: 11/10/20

Pharmacy Benefit Manager Regulatory Issues (B) Subgroup  
Conference Call  
October 29, 2020

The Pharmacy Benefit Manager Regulatory Issues (B) Subgroup of the Regulatory Framework (B) Task Force met via conference call Oct. 29, 2020. The following Subgroup members participated: TK Keen, Chair (OR); Martin Swanson, Vice Chair (NE); Lori K. Wing-Heier, Sarah Bailey and Chris Murray (AK); Yada Horace (AL); Marjorie Farmer (AR); Bruce Hinze (CA); Andria Seip (IA); Vicki Schmidt (KS); Daniel McIlwain and DJ Wasson (KY); Jeffrey Zewe (LA); Mary Kwei (MD); Chad Arnold (MI); Amy Hoyt and Cynthia Amann (MO); David Dachs (MT); Robert Croom (NC); Gale Simon (NJ); Renee Blechner (NM); Michael Humphreys (PA); Rachel Jrade-Rice (TN); Don Beatty (VA); Jennifer Kreidler and Ron Pastuch (WA); Nathan Houdek and Jennifer Stegall (WI); Ellen Potter (WV); and Denise Burke (WY).

1. Adopted a PBM Model

Mr. Keen said following the Subgroup's Oct. 22 meeting, NAIC staff circulated a revised draft of the proposed new [State] Pharmacy Benefit Manager Licensure and Regulation Model Act (PBM model) reflecting the Subgroup's discussion during that meeting. He also noted that the addition of additional state statutory citations in the drafting note for Section 8—Regulations. He asked for additional comments.

Commissioner Schmidt asked if the Subgroup plans to incorporate the additional state statutory citations provided by the National Community Pharmacists Association (NCPA) in its comment letter to the Subgroup. Mr. Keen suggested that the Subgroup add those additional citations, but not include the commentary related to those citations that the NCPA included in its comment letter. After discussion, Mr. Hinze made a motion, seconded by Commissioner Schmidt, to add the NCPA state statutory citations to the draft without the suggested commentary. The motion passed unanimously. Mr. Keen said additional state statutory citations may be added as the draft moves through the adoption process.

Mr. Hinze made a motion, seconded by Mr. Humphreys, to adopt the draft PBM model (Attachment Three-A) and forward it to the Regulatory Framework (B) Task Force for its consideration. The motion passed unanimously.

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

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*Adopted by the Health Insurance and Managed Care (B) Committee - TBD*  
*Adopted by the Regulatory Framework (B) Task Force – TBD*  
*Adopted by the Pharmacy Benefit Manager Regulatory Issues (B) Subgroup – Oct. 29, 2020*

Draft: 10/29/20  
*A new model*

Comments are being requested on this draft. Comments should be sent by email only to Jolie Matthews at jmatthews@naic.org.

## **[STATE] PHARMACY BENEFIT MANAGER LICENSURE AND REGULATION MODEL ACT**

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### **Section 1. Short Title**

This Act shall be known and may be cited as the [State] Pharmacy Benefit Manager Licensure and Regulation Act.

### **Section 2. Purpose**

- A. This Act establishes the standards and criteria for the licensure and regulation of pharmacy benefit managers providing claims processing services or other prescription drug or device services for health benefit plans.
- B. The purpose of this Act is to:
  - (1) Promote, preserve, and protect the public health, safety and welfare through effective regulation and licensure of pharmacy benefit managers;
  - (2) Promote the solvency of the commercial health insurance industry, the regulation of which is reserved to the states by the McCarran-Ferguson Act (15 U.S.C. §§ 1011 – 1015), as well as provide for consumer savings, and fairness in prescription drug benefits;
  - (3) Provide for powers and duties of the commissioner; and
  - (4) Prescribe penalties and fines for violations of this Act.

### **Section 3. Definitions**

For purposes of this Act:

- A. “Claims processing services” means the administrative services performed in connection with the processing and adjudicating of claims relating to pharmacist services that include:
  - (1) Receiving payments for pharmacist services;
  - (2) Making payments to pharmacists or pharmacies for pharmacist services; or

(3) Both paragraphs (1) and (2).

B. “Commissioner” means the insurance commissioner of this state.

**Drafting Note:** Use the title of the chief insurance regulatory official wherever the term “commissioner” appears.

C. “Covered person” means a member, policyholder, subscriber, enrollee, beneficiary, dependent or other individual participating in a health benefit plan.

D. “Health benefit plan” means a policy, contract, certificate or agreement entered into, offered or issued by a health carrier to provide, deliver, arrange for, pay for or reimburse any of the costs of [physical, mental or behavioral] health care services.

E. “Health carrier” means an entity subject to the insurance laws and regulations of this state, or subject to the jurisdiction of the commissioner, that contracts or offers to contract or enters into an agreement to provide, deliver, arrange for, pay for or reimburse any of the costs of health care services, including a sickness and accident insurance company, a health insurance company, a health maintenance organization, a hospital and health service corporation, or any other entity providing a plan of health insurance, health benefits, or health care services.

**Drafting Note:** States that license health maintenance organizations pursuant to statutes other than the insurance statutes and regulations, such as the public health laws, will want to reference the applicable statutes instead of, or in addition to, the insurance laws and regulations.

F. “Other prescription drug or device services” means services other than claims processing services, provided directly or indirectly, whether in connection with or separate from claims processing services, including, but not limited to:

- (1) Negotiating rebates, discounts or other financial incentives and arrangements with drug companies;
- (2) Disbursing or distributing rebates;
- (3) Managing or participating in incentive programs or arrangements for pharmacist services;
- (4) Negotiating or entering into contractual arrangements with pharmacists or pharmacies, or both;
- (5) Developing and maintaining formularies;
- (6) Designing prescription benefit programs; or
- (7) Advertising or promoting services.

G. “Pharmacist” means an individual licensed as a pharmacist by the [state] Board of Pharmacy.

H. “Pharmacist services” means products, goods, and services or any combination of products, goods and services, provided as a part of the practice of pharmacy.

I. “Pharmacy” means the place licensed by the [state] Board of Pharmacy in which drugs, chemicals, medicines, prescriptions and poisons are compounded, dispensed or sold at retail.

J. (1) “Pharmacy benefit manager” means a person, business or entity, including a wholly or partially owned or controlled subsidiary of a pharmacy benefit manager, that provides claims processing services or other prescription drug or device services, or both, to covered persons who are residents of this state, for health benefit plans.

- (2) “Pharmacy benefit manager” does not include:
- (a) A health care facility licensed in this state;
  - (b) A health care professional licensed in this state;
  - (c) A consultant who only provides advice as to the selection or performance of a pharmacy benefit manager; or
  - (d) A health carrier to the extent that it performs any claims processing and other prescription drug or device services exclusively for its enrollees.

#### **Section 4. Applicability**

- A. This Act shall apply to a contract or health benefit plan issued, renewed, recredentialed, amended or extended on or after the effective date of this Act, including any health carrier that performs claims processing or other prescription drug or device services through a third party.

**Drafting Note:** States may want to consider adding language to Subsection A above or Section 10—Effective Date providing additional time for pharmacy benefit managers to come into compliance with the requirements of this Act.

- B. As a condition of licensure, any contract in existence on the date the pharmacy benefit manager receives its license to do business in this state shall comply with the requirements of this Act.
- C. Nothing in this Act is intended or shall be construed to conflict with existing relevant federal law.

#### **Section 5. Licensing Requirement**

- A. A person may not establish or operate as a pharmacy benefit manager in this state for health benefit plans without first obtaining a license from the commissioner under this Act.
- B. The commissioner may adopt regulations establishing the licensing application, financial and reporting requirements for pharmacy benefit managers under this Act.

**Drafting Note:** States that are restricted in their rulemaking to only what is prescribed in statute may want to consider including in this section specific financial standards required for a person or organization to obtain a license to operate as a pharmacy benefit manager in this state.

- C. A person applying for a pharmacy benefit manager license shall submit an application for licensure in the form and manner prescribed by the commissioner.

**Drafting Note:** States may want to consider reviewing their third party administrator statute if a state wishes to specify what documents must be provided to the commissioner to obtain a pharmacy benefit manager license in the state.

- D. A person submitting an application for a pharmacy benefit manager license shall include with the application a non-refundable application fee of \$[X].
- E. The commissioner may refuse to issue or renew a license if the commissioner determines that the applicant or any individual responsible for the conduct of affairs of the applicant is not competent, trustworthy, financially responsible or of good personal and business reputation or has been found to have violated the insurance laws of this state or any other jurisdiction, or has had an insurance or other certificate of authority or license denied or revoked for cause by any jurisdiction.
- F. (1) Unless surrendered, suspended or revoked by the commissioner, a license issued under this section shall remain valid as long as the pharmacy benefit manager continues to do business in this state

and remains in compliance with the provisions of this act and any applicable rules and regulations, including the payment of an annual license renewal fee of \$[X] and completion of a renewal application on a form prescribed by the commissioner.

- (2) Such renewal fee and application shall be received by the commissioner on or before [x] days prior to the anniversary of the effective date of the pharmacy benefit manager's initial or most recent license.

**Section 6. Gag Clauses and Other Pharmacy Benefit Manager Prohibited Practices**

- A. In any participation contracts between a pharmacy benefit manager and pharmacists or pharmacies providing prescription drug coverage for health benefit plans, no pharmacy or pharmacist may be prohibited, restricted or penalized in any way from disclosing to any covered person any healthcare information that the pharmacy or pharmacist deems appropriate regarding:
  - (1) The nature of treatment, risks or alternative thereto;
  - (2) The availability of alternate therapies, consultations, or tests;
  - (3) The decision of utilization reviewers or similar persons to authorize or deny services;
  - (4) The process that is used to authorize or deny healthcare services or benefits; or
  - (5) Information on financial incentives and structures used by the insurer.
- B. A pharmacy benefit manager may not prohibit a pharmacy or pharmacist from discussing information regarding the total cost for pharmacist services for a prescription drug or from selling a more affordable alternative to the covered person if a more affordable alternative is available.
- C. A pharmacy benefit manager contract with a participating pharmacist or pharmacy may not prohibit, restrict, or limit disclosure of information to the commissioner, law enforcement or state and federal governmental officials, provided that:
  - (1) The recipient of the information represents it has the authority, to the extent provided by state or federal law, to maintain proprietary information as confidential; and
  - (2) Prior to disclosure of information designated as confidential the pharmacist or pharmacy:
    - (a) Marks as confidential any document in which the information appears; or
    - (b) Requests confidential treatment for any oral communication of the information.
- D. A pharmacy benefit manager may not terminate the contract of or penalize a pharmacist or pharmacy due to pharmacist or pharmacy:
  - (1) Disclosing information about pharmacy benefit manager practices, except for information determined to be a trade secret, as determined by state law or the commissioner; or
  - (2) Sharing any portion of the pharmacy benefit manager contract with the commissioner pursuant to a complaint or a query regarding whether the contract is in compliance with this Act.
- E. (1) A pharmacy benefit manager may not require a covered person purchasing a covered prescription drug to pay an amount greater than the lesser of the covered person's cost-sharing amount under the terms of the health benefit plan or the amount the covered person would pay for the drug if the covered person were paying the cash price.

- (2) Any amount paid by a covered person under paragraph (1) of this subsection shall be attributable toward any deductible or, to the extent consistent with section 2707 of the Public Health Service Act, the annual out-of-pocket maximums under the covered person's health benefit plan.

## **Section 7. Enforcement**

- A. The commissioner shall enforce compliance with the requirements of this Act.
- B. (1) The commissioner may examine or audit the books and records of a pharmacy benefit manager providing claims processing services or other prescription drug or device services for a health benefit plan to determine compliance with this Act.

**Drafting Note:** States may want to consider including a reference to the cost of examinations in the *Model Law on Examinations* (#390).

**Drafting Note:** States may want to consider incorporating their existing market conduct examination statutes into this Act rather than relying on the examination authority provided under this section.

- (2) The information or data acquired during an examination under paragraph (1) is:
- (a) Considered proprietary and confidential;
  - (b) Not subject to the [Freedom of Information Act] of this state;
  - (c) Not subject to subpoena; and
  - (d) Not subject to discovery or admissible in evidence in any private civil action.
- C. The commissioner may use any document or information provided pursuant to Section 6C of this Act or Section 6D of this Act in the performance of the commissioner's duties to determine compliance with this Act.
- D. The commissioner may impose a penalty on a pharmacy benefit manager or the health carrier with which it is contracted, or both, for a violation of this Act. The penalty may not exceed [insert appropriate state penalty] per entity for each violation of this Act.

**Drafting Note:** If an appeals process is not otherwise provided, a state should consider adding such a provision to this section.

## **Section 8. Regulations**

The commissioner may adopt regulations regulating pharmacy benefit managers that not inconsistent with this Act.

**Drafting Note:** This Act is primarily intended to establish licensing standards for pharmacy benefit managers (PBMs). A number of states have enacted statutes or made suggestions that extend into the regulation of pharmacy benefit manager business practices. The provisions below, which are followed by citations to state law where applicable, provide topic areas that states pursuing this Act may wish to consider in their proposed legislation:

- (1) PBM network adequacy (Ark. Code 23-92-505 and Okla. Stat. 36-6961) (Also, see provisions in the *Health Carrier Prescription Drug Benefit Management Model Act* (#22) and the *Health Benefit Plan Network Access and Adequacy Model Act* (#74));
- (2) Prohibited market conduct practices (Ark. Code 23-92-506; MD. ANN. CODE § 15-1642; N.M. Stat. 59A-61-5 and 59A-61-7; Oregon Rev. Stat. §§ 735.534 through 735.552; and South Carolina Code §38-71-2230(A)(1));



- (3) Data reporting requirements under state price-gouging laws;
- (4) Rebates (MD. ANN. CODE § 15-1624 and Texas Insurance Code §1369.502);
- (5) Prohibitions and limitations on the corporate practice of medicine (CPOM);
- (6) Compensation (Ark. Code 23-92-506(b)(5)(A) and N.J.S.A. 17B:27F-8 (New Jersey));
- (7) Procedures for pharmacy audits conducted by or on behalf of a PBM (Del. Ins. Code Chapter 33A §§ 3301A – 3310A; MD. ANN. CODE § 15-1629; Oregon Rev. Stat. §§ 735.540 through 735.552; and 40 PA. CONS. STAT. §§ 4511-4514);
- (8) Medical loss ratio (MLR) compliance;
- (9) Affiliate information-sharing (Ga. Code § 26-4-119 and § 33-64-11(a)(8);
- (10) Lists of health benefit plans administered by a PBM in this state (New Hampshire Rev Stat § 402-N:6)
- (11) Reimbursement lists or payment methodology used by PBMs (Ark. Code § 17-92-507; Del. Ins. Code Chapter 33A §§ 3321A – 3324A; Kansas Rev Stat §§ 40-3829 - 40-3830; 24-A Maine Rev. Stat. Ann. Chapter 56-C; Colo. Rev Stat. § 25-37-103.5; MD. ANN. CODE § 15-1628.1 and §15-1628.2; N.J.S.A. §17B:27F-2 (New Jersey); and Oregon Rev. Stat. § 735.534 and § 735.536);
- (12) Prohibiting clawbacks (Ala. Code § 27-45A-5; MD. ANN. CODE § 15-1628.3; Minn. Stat. 62W.13; N.J.S.A. 17B:27-7 (New Jersey); and Oregon Rev. Stat. § 735.534);
- (13) Affiliate compensation (Colo. Rev. Stat. § 10-16-122.3 and Ga. Code § 26-4-119 and § 33-64-11(a)(7));
- (14) Prohibiting spread pricing (LA. REV. STAT. ANN § 22:1867 and Va. Code § 38.2-3467(D)); and
- (15) Transparency provisions (24-A Maine Rev. Stat. Ann. Chapter 56-C and Texas Insurance Code § 1369.502).

## **Section 9. Severability**

If any provision of this Act, or the application of the provision to any person or circumstance shall be held invalid, the remainder of this Act, and the application of the provision to persons or circumstances other than those to which it is held invalid, shall not be affected.

## **Section 10. Effective Date**

This Act shall be effective [insert date]. A person doing business in this state as a pharmacy benefit manager on or before the effective date of this Act shall have [six (6)] months following [insert date that the Act is effective] to come into compliance with the requirements of this Act.

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Draft: 11/5/20

Pharmacy Benefit Manager Regulatory Issues (B) Subgroup  
Conference Call  
October 22, 2020

The Pharmacy Benefit Manager Regulatory Issues (B) Subgroup of the Regulatory Framework (B) Task Force met via conference call Oct. 22, 2020. The following Subgroup members participated: TK Keen, Chair (OR); Laura Arp and Martin Swanson, Vice Chairs (NE); Sarah Bailey and Chris Murray (AK); Yada Horace (AL); Marjorie Farmer (AR); Bruce Hinze (CA); Andria Seip (IA); Vicki Schmidt (KS); DJ Wasson (KY); Jeffrey Zewe (LA); Mary Kwei (MD); Chad Arnold (MI); Andrew Kleinendorst (MN); Cynthia Amann (MO); David Dachs (MT); Robert Croom (NC); Gale Simon (NJ); Paige Duhamel (NM); Michael Humphreys (PA); Rachel Irade-Rice (TN); Don Beatty (VA); Jennifer Kreidler and Ron Pastuch (WA); Nathan Houdek and Jennifer Stegall (WI); Ellen Potter (WV); and Jeff Rude and Denise Burke (WY).

1. Discussed the Revised PBM Model

Mr. Keen said that following the Subgroup's Oct. 8 meeting, he and Ms. Arp reviewed the revised proposed new [State] Pharmacy Benefit Manager Licensure and Regulation Model Act (PBM model) reflecting the Subgroup's discussion of the Sept. 1 comments. He said based on that review, he and Ms. Arp found a few issues for the Subgroup's discussion during today's meeting. He said he would like to resolve these issues during the meeting and send out a clean copy of the draft model for the Subgroup's adoption during its next meeting in order to forward it to the Regulatory Framework (B) Task Force for its consideration during its Nov. 19 meeting.

Mr. Keen said the first issue concerns the definition of "covered entity" in Section 3C—Definitions. He said the definition of "covered entity" is similar to the definition of "health carrier" used in the *Health Carrier Prescription Drug Benefit Management Model Act* (#22). He asked if the Subgroup wanted to retain this term and definition or replace it with the term "health carrier," as defined in Model #22. The Subgroup discussed the issue. After discussion, the Subgroup agreed that it should be consistent with the terms used in Model #22 and other NAIC models. Mr. Hinze made a motion, seconded by Mr. Humphreys, to delete the definition of "covered entity" in Section 3C and replace it with the defined term "health carrier," as used in Model #22. The motion passed unanimously.

Mr. Keen said the next issue concerns Section 6B—Gag Clauses and Other Pharmacy Benefit Manager Prohibited Practices. He said this provision appears to be redundant because of Section 6C and should be deleted. The Subgroup agreed. Mr. Hinze made a motion, seconded by Ms. Seip, to delete Section 6B and renumber Section 6 accordingly. The motion passed unanimously.

Mr. Keen said the last issue concerns the legal citations for the drafting note in Section 8—Regulations. He requested that the Subgroup members submit any additional citations from their state laws to NAIC staff for inclusion in the draft to be voted on during the Subgroup's next meeting.

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

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Draft: 11/3/20

Pharmacy Benefit Manager Regulatory Issues (B) Subgroup  
Conference Call  
October 8, 2020

The Pharmacy Benefit Manager Regulatory Issues (B) Subgroup of the Regulatory Framework (B) Task Force met via conference call Oct. 8, 2020. The following Subgroup members participated: TK Keen, Chair (OR); Laura Arp and Martin Swanson, Vice Chairs (NE); Sarah Bailey and Chris Murray (AK); Anthony L. Williams and Yada Horace (AL); Marjorie Farmer (AR); Bruce Hinze (CA); Andria Seip (IA); Vicki Schmidt (KS); DJ Wasson (KY); Jeffrey Zewe (LA); Mary Kwei (MD); Chad Arnold (MI); Andrew Kleinendorst (MN); Amy Hoyt (MO); David Dachs (MT); Robert Croom (NC); Gale Simon (NJ); Paige Duhamel (NM); Michael Humphreys (PA); Rachel Jrade-Rice (TN); Don Beatty (VA); Jennifer Kreidler and Ron Pastuch (WA); Nathan Houdek and Jennifer Stegall (WI); Jamie Taylor (WV); and Denise Burke (WY).

1. Continued Discussion of the Sept. 1 Comments Received on the Draft PBM Model

Mr. Keen said that during the Subgroup's Oct. 1 meeting, the Subgroup agreed to revisit suggested revisions to Section 6—Gag Clauses Prohibited of the proposed new [State] Pharmacy Benefit Manager Licensure and Regulation Model Act (PBM model) (*see NAIC Proceedings – Summer 2020, Regulatory Framework (B) Task Force, Attachment Six-A*). He said that as the Subgroup requested, California, Kansas, New Mexico and Pennsylvania met and developed language for revising Section 6D and adding a new Section 6E to address confidentiality concerns, but not giving a pharmacy benefit manager (PBM) blanket authority to decide what information a pharmacy or pharmacist may disclose to the commissioner, law enforcement, and state and federal officials under certain specified circumstances. Mr. Humphries said the suggested language is a blend of language from Tennessee and New Mexico existing law. The Subgroup discussed the suggested language.

Mr. Hinze made a motion, seconded by Ms. Kwei, to adopt the suggested language with a few revisions suggested by the Subgroup. The motion passed unanimously.

The Subgroup next discussed adding language to Section 7—Enforcement suggested by Mr. Croom that would give the commissioner the authority to use any document or information provided under Section 6 in the performance of the commissioner's duties to determine compliance with this Act.

Mr. Hinze made a motion, seconded by Commissioner Schmidt, to add the suggested language to Section 7. The motion passed unanimously.

The Subgroup continued its discussion of the Sept. 1 comments. No comments were received on Section 9—Severability or Section 10—Effective Date. Mr. Keen said several stakeholders submitted comments suggesting the Subgroup add new sections. He said that many of these new sections involved PBM transparency and business practices. He asked for comments.

Amy Killelea (National Alliance of State and Territorial AIDS Directors—NASTAD) said PBM cost transparency is an important issue for the Subgroup to consider and should be incorporated into the new model. She said the NAIC consumer representatives included in its comments to the Subgroup suggested language for a new section in the draft on PBM cost transparency. She said the suggested language for this new section is based on Connecticut and Washington provisions on the subject. Carl Schmid (HIV + Hepatitis Policy Institute) reminded the Subgroup that its charge includes considering the inclusion of provisions on PBM prescription drug pricing and cost transparency in the new model. Daniel Blaney-Koen (American Medical Association—AMA) expressed support for including a cost transparency provision into the new model. He also said the AMA suggested in its comments the Subgroup include a new section prohibiting PBMs from interfering with the patient-physician relationship with respect to prescribing or dispensing prescription drugs.

The Subgroup discussed the NAIC consumer representatives' suggestion to add a new section on PBM cost transparency. Ms. Farmer said Arkansas has a rebate data collection requirement in its law. She said the Arkansas Department of Insurance (DOI) has had issues with the volume and breadth of data that it is required to collect and receive. Mr. Keen said he has heard from states on both sides—wanting to include in the new model and not wanting to include in the new model. He suggested adding transparency provisions to the list of provisions in the Section 8—Regulations drafting note the states can consider for inclusion in their laws. Mr. Hinze expressed support for adding transparency to the list in the Section 8 drafting note. After additional discussion, the Subgroup agreed to accept Mr. Keen's suggestion to add transparency to the list in the Section 8 drafting note.

Mr. Keen said the Subgroup needs to revisit Section 3—Definitions to determine if any changes need to be made based on the revisions the Subgroup made to the draft's substantive sections. He said that he and Ms. Arp will conduct this review. Mr. Keen said he hopes the Subgroup can review the revised draft and vote to send it to the Regulatory Framework (B) Task Force for its consideration during its next meeting Oct. 15.

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

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Draft: 10/14/20

Pharmacy Benefit Manager Regulatory Issues (B) Subgroup  
Conference Call  
October 1, 2020

The Pharmacy Benefit Manager Regulatory Issues (B) Subgroup of the Regulatory Framework (B) Task Force met via conference call Oct. 1, 2020. The following Subgroup members participated: TK Keen, Chair (OR); Martin Swanson and Laura Arp, Vice Chairs (NE); Lori K. Wing-Heier, Sarah Bailey and Chris Murray (AK); Anthony L. Williams and Yada Horace (AL); William Lacy and Marjorie Farmer (AR); Bruce Hinze (CA); Howard Liebers (DC); Andria Seip (IA); Vicki Schmidt (KS); Daniel McIlwain and DJ Wasson (KY); Jeffrey Zewe (LA); Mary Kwei (MD); Chad Arnold (MI); Andrew Kleinendorst (MN); Chlora Lindley-Myers and Amy Hoyt (MO); David Dachs (MT); Robert Croom (NC); Gale Simon (NJ); Paige Duhamel (NM); Michael Humphreys (PA); Rachel Jrade-Rice (TN); Don Beatty (VA); Jennifer Kreidler and Ron Pastuch (WA); Jennifer Stegall (WI); Tonya Gillespie (WV); and Jeff Rude and Denise Burke (WY). Also participating was: Phil Keller (VT).

1. Continued Discussion of the Sept. 1 Comments Received on the Draft PBM Model

Mr. Keen said the Subgroup ended its discussion during its Sept. 24 conference call with the Sept. 1 comments received on Section 6—Gag Clauses Prohibited of the proposed new [State] Pharmacy Benefit Manager Licensure and Regulation Model Act (PBM model) (*see NAIC Proceedings – Summer 2020, Regulatory Framework (B) Task Force, Attachment Six-A*). He said the Subgroup agreed to revisit suggested language for revising Section 6 during this call.

Mr. Humphreys discussed his suggested revisions to Section 6D and a new Section 6E to address concerns raised during the Subgroup's Sept. 24 conference call about a pharmacy benefit manager's (PBM's) ability to prohibit a pharmacy or pharmacist from disclosing information to the commissioner, law enforcement, and state and federal officials under certain circumstances because a PBM decides the information is proprietary or confidential. The Subgroup discussed Mr. Humphreys' suggested revisions. Some Subgroup members expressed concern with the language. Ms. Duhamel suggested that the Subgroup defer deciding on the suggested revisions and review New Mexico's law on the issue. After additional discussion, the Subgroup deferred deciding on Mr. Humphreys' suggested revisions to allow Mr. Humphreys and a few other Subgroup members to work on revising the language for the Subgroup to consider during its next meeting on Oct. 8.

Mr. Humphreys discussed his suggested revisions to Section 6 to incorporate the NAIC consumer representatives' suggested revisions to this section, which would add language to Section 6 prohibiting a PBM from requiring a consumer to pay a cost-sharing amount more than what the consumer would have paid without insurance coverage. Mr. Hinze made a motion, seconded by Mr. Humphreys, to add Mr. Humphreys' suggested language to Section 6. The motion passed unanimously. Mr. Hinze suggested that the Subgroup consider revising Section 6's short title to reflect the just added provisions. After discussion, Mr. Hinze made a motion, seconded by Commissioner Schmidt, to revise Section 6's short title to read "Gag Clauses and Other Prohibited Pharmacy Benefit Manager Prohibited Practices." The motion passed unanimously.

The Subgroup next discussed Section 7—Enforcement. Mr. Humphreys said, as discussed during the Subgroup's Sept. 24 conference call, he suggests adding language to Section 7 specifically permitting the commissioner to impose a penalty on a PBM, a health carrier, or both for a violation of any provision of the proposed PBM model act. Mr. Dachs suggested that the Subgroup consider adding language to Mr. Humphreys' suggested language to specifically add "any other person performing an activity for the PBM." The Subgroup discussed Mr. Humphreys' suggestion and decided that adding such language is unnecessary because it is implied. Kris Hathaway (America's Health Insurance Plans—AHIP) expressed concern with the language giving the commissioner the ability to impose a penalty on both the PBM and the health carrier. She also suggested that the Subgroup add an appeals process. The Subgroup discussed whether to add language providing for an appeals process to Mr. Humphreys' suggested language. After additional discussion, the Subgroup agreed to add a drafting note to Mr. Humphreys' language regarding an appeals process. After additional discussion, Mr. Hinze made a motion, seconded by Mr. Humphreys, to adopt Mr. Humphreys' suggested language, including the suggested drafting note. The motion passed unanimously.

Mr. Keller asked if Section 7A should specifically spell out the commissioner's enforcement authority. The Subgroup discussed his suggestion. After discussion, the Subgroup decided not to include such language because it could unintentionally limit the scope of the commissioner's potential enforcement actions. Mr. Keller suggested adding a drafting note to Section 7B alerting the states that they might want to consider incorporating their existing market conduct examination statutes into this model act.

rather than relying on the examination authority provided in Section 7B. The Subgroup did not make a decision on this suggested language.

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

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Draft: 10/1/20

Pharmacy Benefit Manager Regulatory Issues (B) Subgroup  
Conference Call  
Sept. 24, 2020

The Pharmacy Benefit Manager Regulatory Issues (B) Subgroup of the Regulatory Framework (B) Task Force met via conference call Sept. 24, 2020. The following Subgroup members participated: TK Keen, Chair (OR); Martin Swanson and Laura Arp, Vice Chairs (NE); Sarah Bailey and Chris Murray (AK); William Rodgers and Yada Horace (AL); William Lacy and Marjorie Farmer (AR); Bruce Hinze (CA); Cynthia Banks Radke (IA); Vicki Schmidt (KS); Sharon P. Clark and Daniel McIlwain (KY); Jeffrey Zewe (LA); Mary Kwei (MD); Chad Arnold (MI); Sherri Mortensen-Brown (MN); Chlora Lindley-Myers and Amy Hoyt (MO); David Dachs (MT); Robert Croom (NC); Ralph Boeckman (NJ); Michael Humphreys (PA); Rachel Jade-Rice (TN); Don Beatty (VA); Jennifer Kreidler and Ron Pastuch (WA); Nathan Houdek (WI); Ellen Potter (WV); and Jeff Rude and Denise Burke (WY). Also participating was: Emily Brown (VT).

1. Continued Discussion of the Sept. 1 Comments Received on the Draft PBM Model

Mr. Keen said that during its Sept. 14 conference call, the Subgroup discussed the Sept. 1 comments received on Section 1 through Section 3 of the proposed new [State] Pharmacy Benefit Manager Licensure and Regulation Model Act (PBM model) (*see NAIC Proceedings – Summer 2020, Regulatory Framework (B) Task Force, Attachment Six-A*). He said the Subgroup agreed to revisit those comments after it completes its review and discussion of the comments received on the substantive sections of the PBM model.

The Subgroup next discussed Section 4—Applicability. Carl Schmid (HIV + Hepatitis Policy Institute) pointed out the HIV + Hepatitis Policy Institute’s suggested changes to this section. There was no Subgroup support for making changes to Section 4.

The Subgroup next discussed Section 5—Licensing Requirement. Mr. Hinze expressed support for the NAIC consumer representatives’ suggestion to add the word “first” to Section 5A. Ms. Brown pointed out the Vermont Department of Insurance’s (DOI) suggested revisions to add language to Section 5E clarifying that a commissioner can refuse to renew a pharmacy benefit manager’s (PBM) license in addition to not issuing a license. She said the Vermont DOI also suggests adding language to allow a commissioner to refuse to issue or renew a PBM license if the applicant or any individual responsible for the conduct of the affairs of the applicant “has been found to have violated the insurance laws of this state or any other jurisdiction.” Amy Killelea (National Alliance of State and Territorial AIDS Directors—NASTAD) said the NAIC consumer representatives suggest adding language to Section 5 providing for penalties for any PBM not obtaining a license as required under Section 5. Mr. Schmid said the HIV + Hepatitis Policy Institute submitted comments suggesting revisions to Section 5. He pointed out one suggested revision to Section 5F that would limit the duration of a PBM license to one year. Aaron Turner (URAC) said URAC suggests adding a new provision to Section 5 concerning accreditation if the Subgroup decides to include the option of accreditation to satisfy the PBM model’s requirements. Kris Hathaway (America’s Health Insurance Plans—AHIP) said AHIP suggests a few wordsmithing revisions to Section 5. Clay McClure (Blue Cross Blue Shield Association—BCBSA) said the BCBSA suggests the Subgroup add language to Section 5 establishing an appeal process for PBMs to use if denied licensure. Matthew Magner (National Community Pharmacists Association—NCPA) said the NCPA suggests revising Section 5D to add language specifying that the commissioner set the PBM licensing application fee based on the DOI’s reasonable costs for administering the PBM model.

Mr. Hinze reiterated his support for the NAIC consumer representatives’ suggested revision to Section 5A to add the word “first.” He also expressed support for the Vermont DOI’s suggested revisions to Section 5E, the HIV + Hepatitis Policy Institute’s suggested revisions to Section 5F and the NAIC consumer representatives’ suggested comment to add a penalty provision to the section. Mr. Humphreys said he believes that if the Subgroup adds a penalty provision, such a provision should be added to Section 7—Enforcement. Mr. Hinze agreed with Mr. Humphreys suggestion.

The Subgroup discussed whether to make the suggested revision to Section 5F limiting the duration of a PBM license to one year. Ms. Arp discussed the potential implications of such a requirement and suggestions for the Subgroup to resolve these issues using a different approach than the HIV + Hepatitis Policy Institute’s suggested revision. After additional discussion, the Subgroup decided to defer making a decision on whether to revise Section 5F and revisit it later.

Mr. Hinze made a motion, seconded by Ms. Potter, to revise Section 5A and Section 5E as the Subgroup discussed. The motion passed unanimously.

The Subgroup next discussed Section 6—Gag Clauses Prohibited. The Subgroup noted that some commenters suggested aligning Section 6's language with the federal law on gag clauses. Some Subgroup members expressed support for adding the NAIC consumer representatives' language to Section 6 prohibiting a PBM from requiring consumers to pay a cost-sharing amount more than what a consumer would have paid without insurance coverage. Mr. Humphreys suggested revisions to the language if the Subgroup decided to add it.

Mr. Magner highlighted the NCPA's suggestion to add language to Section 6 that would address prescription drug prices and transparency. He also noted the NCPA's suggested revision to Section 6D to add an additional provision to prohibit a PBM from prohibiting, restricting or limiting a pharmacy or pharmacist from disclosing information when the information is being gathered for public policy purposes. He explained the NCPA's reasoning for the suggested language. The Subgroup discussed the NCPA's suggested revision to Section 6D. Leanne Gassaway (CVS Health) expressed concern with the NCPA's suggested revision because of its potential to permit the disclosure of confidential information in a public setting. After additional discussion, the Subgroup decided to defer making a decision on any revisions to Section 6 to permit Subgroup members and interested parties to submit additional suggestions for the Subgroup's consideration during its next meeting Oct. 1 via conference call.

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

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Draft: 9/29/20

Pharmacy Benefit Manager Regulatory Issues (B) Subgroup  
Conference Call  
Sept. 14, 2020

The Pharmacy Benefit Manager Regulatory Issues (B) Subgroup of the Regulatory Framework (B) Task Force met via conference call Sept. 14, 2020. The following Subgroup members participated: TK Keen, Chair (OR); Martin Swanson and Laura Arp, Vice Chairs (NE); Sarah Bailey (AK); Yada Horace (AL); William Lacy and Marjorie Farmer (AR); Bruce Hinze (CA); Howard Liebers (DC); Andria Seip (IA); Vicki Schmidt (KS); Sharon P. Clark and Daniel McIlwain (KY); Jeffrey Zewe (LA); Mary Kwei (MD); Chad Arnold (MI); Sherri Mortensen-Brown (MN); Chlora Lindley-Myers and Amy Hoyt (MO); David Dachs (MT); Gale Simon (NJ); Paige Duhamel (NM); Michael Humphreys (PA); Rachel Jrade-Rice (TN); Don Beatty (VA); Jennifer Kreidler and Ron Pastuch (WA); Nathan Houdek (WI); Ellen Potter (WV); and Denise Burke (WY). Also participating was: Emily Brown (VT).

1. Discussed Sept. 1 Comments Received on the PBM Model

Mr. Keen said the purpose of the Subgroup's call is to begin discussion of the Sept. 1 comments received on the proposed new [State] Pharmacy Benefit Manager Licensure and Regulation Model Act (PBM model) (*see NAIC Proceedings – Summer 2020, Regulatory Framework (B) Task Force, Attachment Six-A*). He outlined a plan for the Subgroup to review the comments, including meeting weekly via conference call. Commissioner Schmidt asked about a timeline for the Subgroup to complete its work on the proposed new PBM model. Mr. Keen said he hopes the Subgroup can complete its work before the Fall National Meeting.

Mr. Keen suggested that the Subgroup begin its discussion of the Sept. 1 comments with a discussion of the comments received on Section 8—Regulations, specifically Section 8B, which includes a list of potential provisions the states could include in any regulations adopted to implement the proposed PBM model's provisions. Mr. Humphreys said that, as currently drafted, Section 8B would not be something the Pennsylvania legislature would support. He suggested deleting Section 8B and moving its provisions to a drafting note or deleting Section 8B from the draft model entirely and developing a white paper on the provisions listed in it. The Subgroup discussed Mr. Humphreys' suggestion, with some Subgroup members expressing concern and others expressing support.

Amy Killelea (National Alliance of State and Territorial AIDS Directors—NASTAD) agreed with some Subgroup members' comments that Section 8B, as currently written, is not workable, but expressed disagreement with Mr. Humphreys' suggestion for addressing those concerns. She said there is a growing consensus across the states regarding some of the provisions listed in Section 8B. She urged the Subgroup to take a different approach than Mr. Humphreys' suggestion and consider retaining some of the provisions in Section 8B, particularly those related to transparency. Carl Schmid (HIV + Hepatitis Policy Institute) expressed support for Ms. Killelea's comments. He urged the Subgroup to specifically consider retaining the provisions related to rebates. Matthew Magner (National Community Pharmacists Association—NCPA) suggested that the Subgroup work to fill in the language in Section 8B to provide specific language for state legislatures to consider if they decide to include any of the provisions listed in Section 8B in legislation enacting the PBM model. Lauren Rowley (Pharmaceutical Care Management Association—PCMA) expressed support for Mr. Humphreys' suggestion. Kris Hathaway (America's Health Insurance Plans—AHIP) also expressed support for Mr. Humphreys' suggestion. She also cautioned the Subgroup on including language in the PBM model that would affect prescription drug rebates because of plans' use of rebates to save money. Clay McClure (Blue Cross Blue Shield Association—BCBSA) also expressed support for Mr. Humphreys' suggestion.

Mr. Humphreys made a motion, seconded by Ms. Jrade-Rice, to delete Section 8B and move its provisions to the drafting note and amending the drafting note to state: "This Act is primarily intended to establish licensing standards for pharmacy benefit managers (PBMs). A number of states have enacted statutes that extend into the regulation of PBM business practices. The provisions below, which are followed by citations to state law, provide topic areas that states pursuing this Act may wish to consider in their proposed legislation." Commissioner Schmidt expressed concern with removing Section 8B because of the transparency provisions it includes, which could be lost if moved to a drafting note. A few other Subgroup members expressed similar concerns. The motion passed with 16 states in favor of the motion, three states opposed and six states abstaining. Director Lindley-Myers said Missouri voted in favor of the motion based on the NAIC process, which provides that a state is not required to adopt an NAIC model word-for-word. Each state can make changes to an NAIC model that are appropriate for that state and what the state's legislature will or will not pass based on what is best for the state.

The Subgroup next discussed the Sept. 1 comments received on Section 1 through Section 3. Ms. Brown said the Vermont Department of Insurance (DOI) submitted comments on the definition of “health benefit plan” in Section 3E suggesting that the definition of a “health benefit plan” include a stand-alone prescription drug plan. Ms. Killelea asked if the Subgroup could revisit the discussion of the comments received on Section 1 through Section 3 after the Subgroup completes its discussion of the comments received on the draft PBM model’s substantive provisions. She said the changes the Subgroup will make to the substantive provisions will affect the provisions in Section 1 through Section 3. Mr. Keen agreed. The Subgroup discussed additional suggested revisions to Section 1 through Section 3, but after additional discussion, the Subgroup decided to defer making any changes to these sections until after it completes its review and discussion of the comments received on the substantive provisions of the draft PBM model.

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

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