REGULATORY FRAMEWORK (B) TASK FORCE

Regulatory Framework (B) Task Force July 28, 2021, Minutes
   Regulatory Framework (B) Task Force June 15, 2021, Minutes (Attachment One)
       Pharmacy Benefit Manager Regulatory Issues (B) Subgroup New 2021 Charge (Attachment One-A)
   Accident and Sickness Insurance Minimum Standards (B) Subgroup July 12, 2021, Minutes (Attachment Two)
   Accident and Sickness Insurance Minimum Standards (B) Subgroup June 7, 2021 (Attachment Three)
   Mental Health Parity and Addiction Equity Act (MHPAEA) (B) Working Group April 21, 2021, Minutes (Attachment Four)
The Regulatory Framework (B) Task Force met July 28, 2021. The following Task Force members participated: Michael Conway, Chair (CO); Glen Mulready, Vice Chair (OK); Lori K. Wing-Heier represented by Sarah Bailey (AK); Jim L. Ridling represented by Anthony L. Williams and Jennifer Li (AL); Evan G. Daniels represented by Jon Savary and Erin Klug (AZ); Ricardo Lara represented by Tyler McKinney (CA); Andrew N. Mais represented by Jared Kosky (CT); David Altmaier represented by Chris Struk (FL); Doug Ommen represented by Andria Seip (IA); Dean L. Cameron (ID); Dana Popish Severingham represented by Ryan Gillespie (IL); Amy L. Beard represented by Claire Szpara and Alex Peck (IN); Vicki Schmidt (KS); Sharon P. Clark (KY); Gary D. Anderson represented by Kevin Beagan (MA); Eric A. Cioppa represented by Marti Hooper (ME); Anita G. Fox represented by Renee Campbell and Karen Dennis (MI); Grace Arnold represented by Galen Benshoof, Peter Brickwedde, and Sarah Wohlford (MN); Chlora Lindley-Myers (MO); Mike Causey represented by Ted Hamby (NC); Jon Godfried represented by John Arnold and Chrystal Bartuska (ND); Eric Dunning (NE); Chris Nicolopoulos represented by Michelle Heaton (NH); Judith L. French represented by Laura Miller, Theresa Schaefer, and George McNab (OH); Andrew R. Stolfe represented by TK Keen (OR); Jessica K. Altman (PA); Larry D. Deiter (SD); Doug Slape represented by Rachel Bowden, David Bolduc, and Richard Lunsford (TX); Jonathan T. Pike represented by Jaakob Sundberg and Shelley Wiseman (UT); Scott A. White represented by Julie Blauvelt, Bob Grissom, and Bradley Marsh (VA); Mike Kreidler represented by Molly Nollette, Jane Beyer, and Kimberly Tocco (WA); Mark Afable represented by Richard Wicka and Nathan Houdek (WI); and James A. Dodrill represented by Joylynn Fix and Tonya Gillespie (WV). Also participating was: Russell Toal (NM).

1. **Adopted its June 15 and Spring National Meeting Minutes**

The Task Force met June 15 to adopt a new 2021 charge for the Pharmacy Benefit Manager Regulatory Issues (B) Subgroup to develop a white paper on issues related to the state regulation of certain pharmacy benefit manager (PBM) business practices and the effect, if any, of the recent U.S. Supreme Court decision in *Rutledge v. the Pharmaceutical Care Management Association (PCMA)* on these current and emerging state laws and regulations regulating such business practices. The white paper will also examine the role PBMs, pharmacy services administrative organizations (PSAOs), and other prescription drug supply chain entities play in the provision of prescription drug benefits.

Commissioner Altman made a motion, seconded by Commissioner Deiter, to adopt the Task Force’s June 15 (Attachment One) and March 25 (see NAIC Proceedings – Spring 2021, 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 Commissioner Clark, to adopt the following reports: the Accident and Sickness Insurance Minimum Standards (B) Subgroup, including its July 12 (Attachment Two) and June 7 (Attachment Three) minutes; the Employee Retirement Income Security Act (ERISA) (B) Working Group; the Mental Health Parity and Addiction Equity Act (MHPAEA) (B) Working Group, including its April 21 minutes (Attachment Four); and the Pharmacy Benefit Manager Regulatory Issues (B) Subgroup. The motion passed unanimously.

3. **Received a Work Status Update for the ERISA (B) Working Group and the Pharmacy Benefit Manager Regulatory Issues (B) Subgroup**

   a. **ERISA (B) Working Group**

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

Mr. Keen said the Pharmacy Benefit Manager (B) Subgroup plans to hold a few organizational meetings to determine what information it needs to work on its new 2021 charge to develop the white paper. He explained that the Subgroup will not be starting its work from scratch because of its work related to the development of the proposed [State] Pharmacy Benefit Manager Licensure and Regulation Model Act (PBM model), but he anticipates the Subgroup will have to hold informational meetings on subjects that it did not consider during that work. The Subgroup also could establish a few ad hoc groups to work on different aspects of the white paper. Mr. Keen said he anticipates the Subgroup will begin meeting following the Summer National Meeting to develop a work plan. He said some the Subgroup’s first meetings will be regulator-to-regulator meetings to discuss a path forward. Mr. Keen said he plans to provide updates to the Task Force on the Subgroup’s work as it moves forward.

4. Heard an Update on the CHIR’s Work Related to the ACA

Christine Monahan (Center on Health Insurance Reforms—CHIR, Georgetown University’s McCourt School of Public Policy) provided an update on the CHIR’s work related to the federal Affordable Care Act (ACA) and recently enacted federal laws such as the federal No Surprises Act (NSA) and the federal American Rescue Plan Act (ARPA) and other issues of interest to state insurance regulators. She discussed the CHIR’s recent publications, including a 50-state survey of state employee benefit plans and efforts to restrain health care costs. The CHIR received responses from 47 states and interviewed state employee benefit plan administrators in 11 of those states to better understand what these states are doing to address health care costs. The CHIR also recently published issue brief on state actions between March 2020 and March 2021 to expand telemedicine access during COVID-19 and future policy considerations.

Ms. Monahan said the CHIR is researching and expects to release issue briefs or blogs on standardized plans, limited plan sales, state “Easy Enrollment” programs, efforts by select state-based marketplaces (SBMs) to improve health equity, and small group health insurance market trends. She highlighted some of the CHIR’s future work related to NSA implementation, including working with states with existing balance billing laws and technical assistance available to the states and its ongoing work related to network adequacy. Ms. Monahan said the CHIR is closely monitoring federal and state efforts to develop and implement public options. She said the CHIR recently published a blog post for the Commonwealth Fund comparing the laws in Washington, Colorado, and Nevada.

Ms. Monahan said the CHIR is beginning to examine the role of ERISA and its impact on state efforts to address cost containment with respect to employer plans. She said that among other things, the CHIR wants to better understand the legal landscape facing states that want to try to encourage cost containment among employer plans and document current efforts in this area. She said that one goal of this research is for the CHIR to make recommendations on whether and to what extent federal legislative or regulatory changes are needed to better foster cost containment by employer plans. As part of this research effort, the CHIR plans to reach out to stakeholders and conduct interviews in late 2021. She said to let the CHIR know if anyone is interested in this issue or knows of specific stakeholders the CHIR should interview.

5. Heard a Presentation on the NSA IFR and Implications for the States

Katie Keith (Out2Enroll) and Jack Hoadley (Georgetown University Health Policy Institute) presented on the recently issued NSA interim final rule (IFR) and implications for the states. Ms. Keith provided an overview of the NSA’s scope, including what types of plans it covers and where its protections apply. She said the NSA’s IFR was issued July 1 with an effective date of Sept. 13. The IFR was issued jointly by the U.S. Department of Labor (DOL), the U.S. Department of Health and Human Services (HHS), the U.S. Department of the Treasury (Treasury Department), and the U.S. Office of Personnel Management (OPM).

Ms. Keith said the IFR includes provisions focused on both patients and regulated entities. She explained that the patient-focused provisions outline how patients can calculate cost-sharing, include notice-and-consent waivers provisions, and establish a consolidated complaints process. The regulated entities-focused provisions outline how to calculate the qualifying payment amount and include disclosure requirements and provisions related to communications between insurers and providers.

Mr. Hoadley discussed the scope of the NSA’s balance billing protections with respect to the types of providers subject to its requirements. He explained that the NSA applies to emergency care provided in in-network or out-of-network facilities. Specifically, the NSA includes emergency departments and independent free-standing emergency departments. He said the IFR extends the scope of the NSA’s protections to urgent care services licensed by the state for emergency services. Mr. Hoadley also discussed the NSA’s protections with respect to post-stabilization services, including its application regardless of where in a hospital the services are furnished. He said the IFR includes strong patient protections for waivers in
these circumstances, including requirements that: 1) the patient must be able to travel using nonmedical/nonemergency transportation; 2) the patient gives informed consent; and 3) the in-network facility is within a reasonable distance. He also discussed the scope of the NSA’s protections regarding air ambulance services providers.

Mr. Hoadley discussed the NSA’s protections in circumstances where a patient receives non-emergency services from an out-of-network provider while at an in-network facility. He explained what facilities are included in the NSA’s definition of “health care facility” but noted that the IFR does not identify any additional facilities, which leaves open as to whether the NSA’s protections for non-emergency services would apply to other facilities not included in the NSA’s definition, such as urgent care facilities and retail clinics. Mr. Hoadley discussed other clarifying provisions in the IFR regarding services provided by out-of-network providers in an in-network facility.

Mr. Hoadley detailed the notice and consent provisions explaining what a patient can and cannot waive with respect to the NSA’s balance billing protections. Patients can knowingly and voluntarily agree to be balance billed by out-of-network providers but only for: 1) non-emergency care from an out-of-network provider; or 2) out-of-network post-stabilization services. Patients can not waive protections: 1) when there is no in-network provider available; 2) for urgent or unforeseen care; 3) when services are delivered by providers in designated specialties, such as anesthesiology, radiology, hospitalists, or intensivists; and 4) post-stabilization services except for out-of-network post-stabilization services. The IFR includes a draft standard notice and consent form. He said the federal agencies are seeking comment on the draft notice and consent form and are interested in any forms that those states with existing balance billing laws may use.

Mr. Hoadley explained the IFR’s provisions concerning the in-network qualifying payment amount (QPA) for an out-of-network provider. The IFR spells out definitions and methodology for determining the QPA. It also includes additional provisions affecting the QPA, including minimizing the influence of outlier prices that could skew the QPA higher. He pointed out that the IFR does not include the NAIC’s recommendation to base region on qualified health plan (QHP) rating areas, but uses another principle suggested—metropolitan statistical areas (MSAs) and non-MSA areas in a state. Mr. Hoadley also explained that the IFR defines what a “specified state law” is for purposes of determining what method will be used to determine the amount of payment to an out-of-network provider, which could be either a payment standard or arbitration or a combination of both. The IFR also specifies that states with self-funded opt-in programs can maintain those programs. If state law does not apply, the NSA applies.

Mr. Hoadley said the IFR confirms that state departments of insurance (DOIs) are the primary enforcers of provisions that apply to insurers and fully insured health products. The HHS will enforce the NSA’s requirements in states that fail to substantially enforce the law. The DOL will enforce the NSA’s provisions for self-funded group health plans. The same enforcement framework is established with respect to providers, including air ambulances. Mr. Hoadley noted that the NSA and the IFR are silent on which state agency is to enforce the NSA’s provider provisions.

Mr. Hoadley discussed key considerations for the states, particularly that state laws can be more protective of consumers if the state law does not “prevent the application of federal law.” The IFR includes a few examples of this. He also noted that the IFR does not specify which state laws qualify as “specified state law” or when the “specified state law” would apply. He explained that the IFR sets out specific scenarios in determining whether the “specified state law” would apply or the NSA.

Ms. Keith said it is anticipated that the federal government will issue additional NSA rules in 2021, including federal rules on the independent dispute resolution process (interim final rule) and enforcement and air ambulance data reporting (proposed rule). She said additional federal rulemaking will occur over time on other NSA requirements, such as accurate provider directories, gag clauses, and PBM reporting requirements. However, these rules will not be promulgated prior to the NSA’s 2022 effective date.

Commissioner Mulready asked about how the NSA and the IFR treats emergency services and urgent care services. He noted Mr. Hoadley’s discussion about whether urgent care facilities will be considered “health care facilities” for purposes of the NSA. Mr. Hoadley said the NSA focuses on emergency services provided in relation to an emergency department—not urgent care services provided in an urgent care center unless the state licenses the urgent care center to provide emergency services. He said that because of this, if a consumer receives services at an out-of-network urgent care center, then the NSA would not provide balance billing protections because the urgent care center will be considered to have provided non-emergency services, not emergency services.

Commissioner Conway asked about the IFR’s provisions regarding the circumstances when a consumer can waive the NSA’s balance billing protections. He said that in Colorado, essentially any provider can ask a consumer to waive Colorado’s balance billing protections. He asked Mr. Hoadley if the NSA, which restricts the ability of certain types of providers from asking
consumers to waive its balance billing protections, would prevail over Colorado’s law. Mr. Hoadley said that although the IFR does not strictly detail this situation, he believes that the NSA would most likely prevail.

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

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

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

Commissioner Conway said that during the Task Force’s March 18 meeting, the Task Force discussed and agreed to consider a new 2021 charge for the Pharmacy Benefit Manager Regulatory Issues (B) Subgroup to develop a white paper consistent with some of the comments received on the draft [State] Pharmacy Benefit Manager Licensure and Regulation Model Act (PBM model). He said that prior to the meeting, NAIC staff distributed a draft of the proposed charge for the Subgroup to “develop a white paper to: 1) analyze and assess the role PBMs play in the provision of prescription drug benefits; 2) identify, examine, and describe current and emerging state regulatory approaches to PBM business practices, such as price transparency and reporting requirements, rebating, and spread pricing, including the implications of the Rutledge vs. Pharmaceutical Care Management Association (PCMA) decision on such business practices; and 3) discuss any challenges, if any, the states have encountered in implementing such laws and/or regulations.”

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

Mr. Wake expressed support for Mr. Swanson’s comments suggesting the white paper examine the entire prescription drug supply chain. He also agreed with Mr. Swanson’s comments concerning the Rutledge decision. Mr. Kosky also agreed with Mr. Swanson’s comments with respect to examining and understanding the entire prescription drug supply chain to avoid the balloon effect of making regulatory changes to one part of the supply chain, which might affect costs and unintentionally shifting that change in cost to another part of the chain. Additional Task Force members expressed support for broadening the proposed charge to include other entities in the prescription drug supply chain. The Task Force also discussed, but it deferred
deciding on, whether the Pharmacy Benefit Manager Regulatory Issues (B) Subgroup’s name would have to be changed to reflect the addition of other entities involved in the prescription drug supply chain.

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

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

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

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

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

Commissioner Conway said that based on the discussion, he believes the Task Force has consensus to revise the proposed charge to add the following language from the PCMA’s comment letter: “Pharmacy Services Administrative Organizations (PSAOs) and other supply chain entities.” No one disagreed. Mr. Hinze made a motion, seconded by Mr. Keen to add the PCMA language to the proposed charge (Attachment One-A). The motion passed unanimously.

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

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Draft: 6/15/21
Adopted by the Health Insurance and Managed Care (B) Committee – June 22, 2021
Adopted by the Regulatory Framework (B) Task Force – June 15, 2021

2021 REVISED 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.

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.

   B. Develop a white paper to: 1) analyze and assess the role PBMs, Pharmacy Services Administrative Organizations (PSAOs), and other supply chain entities, play in the provision of prescription drug benefits; 2) identify, examine and describe current and emerging state regulatory approaches to PBM business practices, such as price transparency and reporting requirements, rebating and spread pricing, including the implications of the *Rutledge vs. Pharmaceutical Care Management Association (PCMA)* decision on such business practices; and 3) discuss any challenges, if any, the states have encountered in implementing such laws and/or regulations.

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

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Draft: 7/23/21

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

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

1. Discussed Revisions to Model #171

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

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

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

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

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

No comments were received on Section 4—Effective Date.

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

Ms. Arp suggested that the Subgroup consider revising the language to state, “short-term, limited-duration coverage” for consistency with Model #170. Ms. Bowden said she does not have an objection to Ms. Arp’s suggestion, but she said the Subgroup needs to keep in mind the idea of adding “certificate,” as appropriate, when using the term “policy.” She suggested that the Subgroup might want to consider adding a definition of “policy,” which would include the term “certificate.” The Subgroup discussed this issue and the issue of having two definition sections—one for definitions of terms used in Model #171
and the other for terms used in the policy, which is currently Section 5. Ms. Arp pointed out that Model #170 includes a definition of “policy.” She said if the Subgroup wants to find a term for “policy” that will also mean “certificate” or other similar terms, then it would have to find another term to use.

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

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

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

Having no further business, the Accident and Sickness Insurance Minimum Standards (B) Subgroup adjourned.
Draft: 6/14/21

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

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

1. Discussed the Model #171 Working Draft

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

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

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

Ms. Arp asked for clarity about the term “preexisting condition” in Section 5L. Chris Petersen (Arbor Strategies LLC) explained that there appeared to be some confusion among Subgroup members when this term was discussed in 2019. He said the Subgroup should be cognizant of the fact that Section 5 is not a typical “definitions” section. He said Section 5 is a policy definitions section, which means the terms “defined” in this section are terms that can be used in policies subject to Model #171’s requirements. The terms in Section 5 are not terms necessarily used in Model #170, but terms that, if included in a policy subject to Model #171’s requirements, the insurer must “define” those terms in the policy consistent with the way the term is “defined” in Section 5 or consistent with state law requirements if those requirements are different from Model #171’s requirements. The Subgroup discussed the potential implications with taking certain approaches to revising the term “preexisting condition” based on stakeholder comments, including the use of the prudent layperson standard or a more objective definition of the term to make it easier for consumers to understand.

Noting that it has been a while since the Subgroup last met, Ms. Arp suggested the Subgroup set a new public comment period ending July 2 to receive comments from stakeholders on Sections 1–7 of Model #171. She said stakeholders who have already submitted comments on those sections may resubmit those comments or submit new comments. She said the Subgroup would meet sometime in mid-July to resume its discussion of revisions to Model #171 based on the comments received by the July 2 public comment deadline. Mr. Petersen reminded the Subgroup that Model #170 has been adopted by the full NAIC membership. He said because of this, during its discussions of revisions to Model #171, the Subgroup should not spend time relitigating provisions already resolved in Model #170. Ms. Arp asked NAIC staff to post a redline version of Model #170 to the Subgroup’s web page to assist the Subgroup in its discussions.
Having no further business, the Accident and Sickness Insurance Minimum Standards (B) Subgroup adjourned.
The MHPAEA (B) Working Group of the Regulatory Framework (B) Task Force met April 21, 2021. The following Working Group members participated: Katie Dzurec, Chair (PA); Jane Beyer, Vice Chair (WA); Crystal Phelps (AR); Erin Klug (AZ); Sherin Ghoddoucy (CA); Cara Cheevers (CO); Kurt Swan (CT); Howard Liebers (DC); Sarah Crittenden (GA); Andria Seip (IA); Ryan Gillespie and Erica Weyhenmeyer (IL); Julie Holmes (KS); Erica Bailey (MD); Andrew Kleinendorst (MN); Jeannie Keller (MT); Rosemary Gillespie, Tracy Biehn and Kathy Shortt (NC); Sara Gerving and Chrystal Bartuska (ND); Tyler Brannen and Michelle Heaton (NH); Ralph Boeckman (NJ); Paige Duhamel and Viara Ianakieva (NM); Todd Oberholtzer, Kyla Dembowski, Molly Mottram, Theresa Schaefer and Marjorie Ellis (OH); Mike Rhoads, Teresa Green and Cuc Nguyen (OK); Alyssa Metivier (RI); Kendall Buchanan (SC); Jill Kruger (SD); Rachel Bowden (TX); Tanji J. Northrup (UT); Brant Lyons (VA); Barbara Belling (WI); Joylynn Fix (WV); and Tana Howard (WY).

1. **Received Updates from the DOL and the CCIIO**

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

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

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

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

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

Ms. Dzurec said the Working Group’s next agenda item concerns a proposed new 2021 charge to the Working Group from the Special (EX) Committee on Race and Insurance to “develop model educational material for state departments of insurance...”
(DOIs) and research disparities in and interplay between mental health parity and access to culturally competent care for people of color and other underrepresented groups.” She said the Working Group included this item on the agenda in preparation for working on this new charge.

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

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

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

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

Ms. Nowak said this multi-year Strategy will focus on four conditions that disproportionately affect communities of color—maternal health, behavioral health, diabetes and cardiovascular conditions. She said the BCBSA will focus first on maternal health, and it intends to focus on behavioral health later this year. She said to assist it in working on the Strategy, the BCBSA convened a national advisory panel of doctors, public health experts, and community leaders to provide guidance.
Lastly, Ms. Nowak discussed BCBS plan examples to address health inequities and behavior health services, such as the Blue Shield of California’s partnership with ScaleLA Foundation, the Center for Youth Wellness, and the Compton Unified School District. The goal of this partnership is to develop and implement initiatives that fill behavioral health gaps in care for adolescents, teens and families in Compton and Premera Blue Cross’ development of public-private partnerships to fund capital grants supporting crisis care and stabilization and ensuring that people are treated at the appropriate level of care.

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

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

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

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