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SENATE BILL 257
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Proposed Conference Committee Substitute S257-PCCS35329-BC-4

Short Title: Medication Cost Transparency Act.

(Public)

Sponsors:

Referred to:

March 15, 2021

1 A BILL TO BE ENTITLED
2 AN ACT TO PROMOTE PRICING TRANSPARENCY FOR PATIENTS AND TO
3 ESTABLISH STANDARDS AND CRITERIA FOR THE REGULATION AND
4 LICENSURE OF PHARMACY BENEFITS MANAGERS PROVIDING SERVICES FOR
5 HEALTH BENEFIT PLANS IN NORTH CAROLINA.

6 The General Assembly of North Carolina enacts:

7 **SECTION 1.(a)** G.S. 58-56A-10 is recodified as G.S. 58-56A-30.

8 **SECTION 1.(b)** Article 56A of Chapter 58 of the General Statutes, as amended by
9 Section 1(a) of this act, reads as rewritten:

10 "Article 56A.

11 "Pharmacy Benefits Management.

12 **"§ 58-56A-1. Definitions.**

13 The following definitions apply in this Article:

14 (1) 340B contract pharmacy. – Any pharmacy under contract with a 340B covered
15 entity to dispense drugs on behalf of the 340B covered entity.

16 (2) 340B covered entity. – Any entity defined in 42 U.S.C. § 256b(a)(4)(A), 42
17 U.S.C. § 256b(a)(4)(C), 42 U.S.C. § 256b(a)(4)(D), 42 U.S.C. §
18 256b(a)(4)(E), 42 U.S.C. § 256b(a)(4)(I), 42 U.S.C. § 256b(a)(4)(J), 42 U.S.C.
19 § 256b(a)(4)(K), 42 U.S.C. § 256b(a)(4)(N), or 42 U.S.C. § 256b(a)(4)(O).

20 (3) Claim. – A request from a pharmacy or pharmacist to be reimbursed for the
21 cost of filling or refilling a prescription for a drug or for providing a medical
22 supply or device.

23 (4) Claims processing service. – The administrative services performed in
24 connection with the processing and adjudicating of claims relating to
25 pharmacist services that include either or both of the following activities:

26 a. Receiving payments for pharmacist services.

27 b. Making payments to pharmacists or pharmacies for pharmacist
28 services.

29 ~~(4)(5)~~ Health benefit plan. – As defined in ~~G.S. 58-50-110(11).~~ This definition
30 specifically excludes the State Health Plan for Teachers and State
31 Employees. ~~G.S. 58-3-167.~~

32 ~~(4a)(6)~~ Insured. – An individual covered by a health benefit plan.



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- 1 ~~(2)~~(7) Insurer. – Any entity that provides or offers a health benefit plan. As defined
2 in G.S. 58-3-167.
- 3 (8) Maximum allowable cost list. – A listing of generic or multiple source drugs
4 used by a pharmacy benefits manager to set the maximum allowable cost on
5 which reimbursement of a pharmacy is made.
- 6 ~~(3)~~(9) Maximum allowable cost price. – The maximum per unit reimbursement for
7 amount that a pharmacy benefits manager will reimburse a pharmacy for the
8 cost of generic or multiple source prescription drugs, medical products, or
9 devices.
- 10 (10) Out-of-pocket costs. – With respect to the acquisition of a drug, the amount to
11 be paid by the insured under the plan or coverage, including any cost-sharing,
12 copayment, coinsurance, or deductible.
- 13 ~~(3a)~~(11) Pharmacist. – A person licensed to practice pharmacy under Article 4A of
14 Chapter 90 of the General Statutes.
- 15 (12) Pharmacist services. – Products, goods, or services provided as a part of the
16 practice of pharmacy.
- 17 ~~(4)~~(13) Pharmacy. – A pharmacy registered with the North Carolina Board of
18 Pharmacy. As defined in G.S. 90-85.3(q).
- 19 ~~(5)~~(14) Pharmacy benefits manager. – An entity who contracts with a pharmacy on
20 behalf of an insurer or third-party administrator to administer or manage
21 prescription drug benefits. benefits to perform any of the following functions:
22 a. Negotiating rebates with manufacturers for drugs paid for or procured
23 as described in this Article.
24 b. Processing claims for prescription drugs or medical supplies or
25 providing retail network management for pharmacies or pharmacists.
26 c. Paying pharmacies or pharmacists for prescription drugs or medical
27 supplies.
- 28 (15) Pharmacy benefits manager affiliate. – A pharmacy or pharmacist that directly
29 or indirectly, through one or more intermediaries, owns or controls or is
30 owned or controlled by a pharmacy benefits manager.
- 31 (16) Pharmacy service administrative organization (PSAO). – An organization that
32 assists community pharmacies and pharmacy benefits managers or third-party
33 payors in achieving administrative efficiencies, including contracting and
34 payment efficiencies.
- 35 ~~(6)~~(17) Third-party administrator. – As defined in G.S. 58-56-2.

36 **"§ 58-56A-2. Licensure.**

37 (a) A person or organization may not establish or operate as a pharmacy benefits manager
38 for health benefit plans in this State without obtaining a license from the Commissioner of the
39 Department of Insurance.

40 (b) The Commissioner shall develop an application for licensure to operate in this State
41 as a pharmacy benefits manager and may charge an initial application fee of two thousand dollars
42 (\$2,000) and an annual renewal fee of one thousand five hundred dollars (\$1,500). The pharmacy
43 benefits manager application form must collect only the following information:

- 44 (1) The name, address, and telephone contact number of the pharmacy benefits
45 manager.
- 46 (2) The name and address of the pharmacy benefits manager's agent for service
47 of process in this State.
- 48 (3) The name and address of each person with management or control over the
49 pharmacy benefits manager.
- 50 (4) The name and address of each person with a beneficial ownership interest in
51 the pharmacy benefits manager.

1 (5) Either (i) a signed statement that, to the best of the applicant's knowledge, no
2 officer with management or control of the pharmacy benefits manager has
3 been convicted of a felony or has violated any requirement of State or federal
4 law applicable to pharmacy benefits management or (ii) a description of any
5 felony or any violation of any requirement of State or federal law applicable
6 to pharmacy benefits management committed by any officer with
7 management or control of the pharmacy benefits manager.

8 (c) Unless otherwise provided for in this Article, an applicant or a pharmacy benefits
9 manager that is licensed to conduct business in the State shall file a notice describing any material
10 modification of the information required under this section.

11 (d) The Commissioner shall adopt rules establishing the licensing and reporting
12 requirements of pharmacy benefits managers consistent with the provisions of this Article.

13 **"§ 58-56A-3. Consumer protections.**

14 (a) A pharmacy or pharmacist shall have the right to provide an insured information
15 regarding the amount of the insured's cost share for a prescription drug. Neither a pharmacy nor
16 a pharmacist shall be penalized by a pharmacy benefits manager for discussing any information
17 described in this section or for selling a lower-priced drug to the insured if one is available.

18 (b) A pharmacy benefits manager shall not, through contract, prohibit a pharmacy from
19 offering and providing direct and limited delivery services to an insured as an ancillary service
20 of the pharmacy, as delineated in the contract between the pharmacy benefits manager and the
21 pharmacy.

22 (b1) A pharmacy benefits manager shall not prohibit a pharmacist or pharmacy from
23 charging a minimal shipping and handling fee to the insured for a mailed or delivered prescription
24 if the pharmacist or pharmacy discloses all of the following to the insured before delivery:

25 (1) The fee will be charged.

26 (2) The fee may not be reimbursed by the health benefit plan, insurer, or pharmacy
27 benefits manager.

28 (3) The charge is specifically agreed to by the health benefit plan or pharmacy
29 benefits manager.

30 (c) A pharmacy benefits manager shall not charge, or attempt to collect from, an insured
31 a ~~co-payment~~ copayment that exceeds the total submitted charges by the network pharmacy.

32 (c1) When calculating an insured's contribution to any out-of-pocket maximum,
33 deductible, copayment, coinsurance, or other applicable cost-sharing requirement, the insurer or
34 pharmacy benefits manager shall include any amounts paid by the insured, or on the insured's
35 behalf, for a prescription that is either:

36 (1) Without an AB-rated generic equivalent.

37 (2) With an AB-rated generic equivalent if the insured has obtained authorization
38 for the drug through any of the following:

39 a. Prior authorization from the insurer or pharmacy benefits manager.

40 b. A step therapy protocol.

41 c. The exception or appeal process of the insurer or pharmacy benefits
42 manager.

43 (c2) For purposes of this section, the term "generic equivalent" means a drug that has an
44 identical amount of the same active ingredients in the same dosage form; meets applicable
45 standards of strength, quality, and purity according to the United States Pharmacopeia or other
46 nationally recognized compendium; and which, if administered in the same amount, would
47 provide comparable therapeutic effects. The term "generic equivalent" does not include a drug
48 that is listed by the United States Food and Drug Administration as having unresolved
49 bioequivalence concerns according to the Administration's most recent publication of approved
50 drug products with therapeutic equivalence evaluations.

1 (d) Any contract for the provision of a network to deliver health care services between a
2 pharmacy benefits manager and insurer shall be made available for review by the Department.

3 ~~(e) The Department shall report to the Attorney General any violations of this section or~~
4 ~~G.S. 58-56A-4 in accordance with G.S. 58-2-40(5).~~

5 **"§ 58-56A-4. Pharmacy and pharmacist protections.**

6 (a) A pharmacy benefits manager may only charge a ~~fee~~ fees or otherwise hold a
7 pharmacy responsible for a fee relating to the adjudication of a claim if the fee is reported on the
8 remittance advice of the adjudicated claim or is set out in contract between the pharmacy benefits
9 manager and the pharmacy. No fee or adjustment for the receipt and processing of a claim, or
10 otherwise related to the adjudication of a claim, shall be charged without a justification on the
11 remittance advice or as set out in contract and agreed upon by the pharmacy or pharmacist for
12 each adjustment or fee. This section shall not apply with respect to claims under an employee
13 benefit plan under the Employee Retirement Income Security Act of 1974 or Medicare Part D.

14 (b) Nothing in this Article shall abridge the right of a pharmacist to refuse to fill or refill
15 a prescription if the pharmacist believes it would be harmful to the patient or is not in the patient's
16 best interest, or if there is a question to the validity of the prescription.

17 (c) A pharmacy or pharmacist shall not be prohibited by a pharmacy benefits manager
18 from dispensing any prescription drug, including specialty drugs dispensed by a credentialed and
19 accredited pharmacy, allowed to be dispensed under a license to practice pharmacy under Article
20 4A of Chapter 90 of the General Statutes.

21 (d) A pharmacy benefits manager shall not penalize or retaliate against a pharmacist or
22 pharmacy for exercising rights provided under this Article. This subsection does not apply to
23 breach of contract between a pharmacy and a pharmacy benefits manager.

24 (e) A claim for pharmacist services may not be retroactively denied or reduced after
25 adjudication of the claim unless any of the following apply:

26 (1) The original claim was submitted fraudulently.

27 (2) The original claim payment was incorrect because the pharmacy or pharmacist
28 had already been paid for the pharmacist services.

29 (3) The pharmacist services were not rendered by the pharmacy or pharmacist.

30 (4) The adjustments were agreed to by the pharmacy or pharmacist.

31 (5) The adjustments were part of an attempt to limit overpayment recovery efforts
32 by a pharmacy benefits manager.

33 (f) Nothing in this section shall be construed to limit overpayment recovery efforts by a
34 pharmacy benefits manager.

35 **"§ 58-56A-5. Maximum allowable cost price.**

36 (a) In order to place a prescription drug on the maximum allowable cost price list, the
37 drug must be available for purchase by pharmacies in North Carolina from national or regional
38 wholesalers, must not be obsolete, and must meet one of the following conditions:

39 (1) The drug is listed as "A" or "B" rated in the most recent version of the United
40 States Food and Drug Administration's Approved Drug Products with
41 Therapeutic Equivalence Evaluations, also known as the Orange Book.

42 (2) The drug has a "NR" or "NA" rating, or a similar rating, by a nationally
43 recognized reference.

44 (b) A pharmacy benefits manager shall adjust or remove the maximum allowable cost
45 price for a prescription drug to remain consistent with changes in the national marketplace for
46 prescription drugs. A review of the maximum allowable cost prices for removal or modification
47 shall be completed by the pharmacy benefits manager at least once every seven business days,
48 and any removal or modification shall occur within seven business days of the review. A
49 pharmacy benefits manager shall provide a means by which the contracted pharmacies may
50 promptly review current prices in an electronic, print, or telephonic format within one business
51 day of the removal or modification.

1 (c) A pharmacy benefits manager shall ensure that dispensing fees are not included in the
2 calculation of maximum allowable cost price.

3 (d) A pharmacy benefits manager shall establish an administrative appeals procedure by
4 which a contracted pharmacy or pharmacist, or a designee, may appeal the provider's
5 reimbursement for a prescription drug subject to maximum allowable cost pricing if the amount
6 of reimbursement for the drug is less than the net amount that the network provider paid to the
7 suppliers of the drug. The reasonable administrative appeal procedure must include all of the
8 following:

9 (1) A dedicated telephone number and email address or website for the purpose
10 of submitting administrative appeals.

11 (2) The ability to submit an administrative appeal regarding the pharmacy
12 benefits plan or program directly to the pharmacy benefits manager or through
13 a pharmacy service administrative organization if the pharmacy service
14 administrative organization has a contract with the pharmacy benefits
15 manager that allows for the submission of appeals.

16 (3) No less than 10 calendar days after the applicable prescription fill date to file
17 an administrative appeal.

18 (4) A period of no more than 10 calendar days after receipt of notice of the filing
19 of the administrative appeal by the pharmacy benefits manager for a decision
20 to be made on the appeal.

21 (5) A requirement that if an appeal is upheld, then, within 10 calendar days of the
22 decision, the pharmacy benefits manager shall take all of the following
23 actions:

24 a. Notify the appellant of the decision.

25 b. Apply the change in the maximum allowable cost effective as of the
26 date the appeal was resolved and make the change effective for all
27 similarly situated pharmacies or pharmacists, as defined by the payor
28 subject to the Maximum Allowable Cost list.

29 c. Permit the appellant to reverse and rebill the claim that was appealed.

30 (6) A requirement that if the appeal is denied, then, within 10 calendar days of the
31 decision, the pharmacy benefits manager shall notify the appellant of the
32 decision and provide all of the following information:

33 a. The reason for denial.

34 b. The National Drug Code number for the prescription drug that is the
35 subject of the appeal.

36 c. The names of the national or regional pharmaceutical wholesalers
37 operating in the State.

38 **"§ 58-56A-15. Pharmacy benefits manager networks.**

39 (a) A pharmacy benefits manager shall not deny the right to any properly licensed
40 pharmacist or pharmacy to participate in a retail pharmacy network on the same terms and
41 conditions of other similarly situated participants in the network.

42 (b) A pharmacist or pharmacy that is a member of a pharmacy service administrative
43 organization that enters into a contract with a health benefit plan issuer or a pharmacy benefits
44 manager on the pharmacy's behalf is entitled to receive from the pharmacy service administrative
45 organization a copy of the contract provisions applicable to the pharmacy, including each
46 provision relating to the pharmacy's rights and obligations under the contract.

47 (c) Termination of a pharmacy or pharmacist from a pharmacy benefits manager network
48 does not release the pharmacy benefits manager from the obligation to make any payment due to
49 the pharmacy or pharmacist for pharmacist services properly rendered according to the contract.
50 This subsection does not apply in cases of fraud, waste, and abuse.

51 **"§ 58-56A-20. Pharmacy benefits manager affiliate disclosure; sharing of data.**

1 A pharmacy benefits manager shall not, in any way that is prohibited by the Health Insurance
2 Portability and Accountability Act of 1996 (HIPAA), transfer or share records relative to
3 prescription information containing patient-identifiable and prescriber-identifiable data to a
4 pharmacy benefits manager affiliate.

5 **"§ 58-56A-21. Claims data provided to health benefit plan.**

6 Upon the request of an insurer offering a health benefit plan that contracts with a pharmacy
7 benefits manager, the pharmacy benefits manager shall provide the insurer with claims data that
8 reflects the total amount the insurer paid to the pharmacy benefits manager under the health
9 benefit plan for a specified outpatient prescription drug, including the ingredient cost and the
10 dispensing fee. The pharmacy benefits manager shall also provide the cost that it paid for the
11 specified outpatient prescription drug, including the ingredient cost and the dispensing fee.

12 **"§ 58-56A-25. Enforcement.**

13 (a) The Commissioner may make an examination of the affairs of any pharmacy benefits
14 manager pursuant to the services that it provides for an insurer or a health benefit plan that are
15 relevant to determining if the pharmacy benefits manager is in compliance with this Article.
16 When making an examination, the Commissioner may retain attorneys, independent actuaries,
17 independent certified public accountants, or other professionals and specialists as examiners. The
18 pharmacy benefits manager shall bear the cost of retaining those persons.

19 (b) Pending, during, and after the examination of any pharmacy benefits manager, the
20 Commissioner shall not make public the information or data acquired, and the information or
21 data acquired during an examination is considered proprietary and confidential and is not a public
22 record under Chapter 132 of the General Statutes.

23 (c) Violations of this Article are subject to the penalties under G.S. 58-56A-30. After
24 notice and hearing, a pharmacy benefits manager may also be subject to revocation of, or a refusal
25 to renew, a license to operate in this State as a result of violations of this Article.

26 **"§ 58-56A-30. Civil Penalties for violations; administrative procedure.**

27 (a) Whenever the Commissioner has reason to believe that a pharmacy benefits manager
28 has violated any of the provisions of this Article with such frequency as to indicate a general
29 business practice, the Commissioner may, after notice and opportunity for a hearing, proceed
30 under the appropriate subsections of this section.

31 (b) If, under subsection (a) of this section, the Commissioner finds a violation of this
32 Article, the Commissioner may order the payment of a monetary penalty ~~as provided in~~
33 ~~subsection (c) of this section~~ or petition the Superior Court of Wake County for an order directing
34 payment of restitution as provided in subsections (d) and (e) of this section, or both. Each day
35 during which a violation occurs constitutes a separate violation.

36 (c) If the Commissioner orders the payment of a monetary penalty pursuant to subsection
37 (b) of this section, the penalty shall not be less than one hundred dollars (\$100.00) nor more than
38 one thousand dollars (\$1,000) per day for each prescription drug resulting from the pharmacy
39 benefit manager's failure to comply with G.S. 58-56A-5. In determining the amount of the
40 penalty, the Commissioner shall consider the degree and extent of harm caused by the violation,
41 the amount of money that inured to the benefit of the violator as a result of the violation, whether
42 the violation was committed willfully, and the prior record of the violator in complying or failing
43 to comply with laws, rules, or orders applicable to the violator. The clear proceeds of the penalty
44 shall be remitted to the Civil Penalty and Forfeiture Fund in accordance with G.S. 115C-457.2.
45 Payment of the civil penalty under this section shall be in addition to payment of any other
46 penalty for a violation of the criminal laws of this State.

47 (d) Upon petition of the Commissioner to the court pursuant to subsection (b) of this
48 ~~section, the court may order the pharmacy benefits manager who committed a violation specified~~
49 ~~in subsection (b) of this section~~ under this Article to make restitution in an amount that would
50 make whole any pharmacist harmed by the violation. The petition may be made at any time and
51 also in any appeal of the Commissioner's order.

1 (e) Upon petition of the Commissioner to the court pursuant to subsection (b) of this
2 section, the court may order the pharmacy benefits manager who committed a violation specified
3 in subsection (b) of this section under this Article to make restitution to the Department for
4 expenses under subsection (f) of this section, incurred in the investigation, hearing, and any
5 appeals associated with the violation in such amount that would reimburse the agency for the
6 expenses. The petition may be made at any time and also in any appeal of the Commissioner's
7 order.

8 (f) The Commissioner may contract with consultants and other professionals with
9 relevant expertise as necessary and appropriate to conduct investigation, hearing, and appeals
10 activities as provided in this section. ~~Such~~ These contracts shall not be subject to G.S. 114-2.3,
11 G.S. 147-17, or Articles 3, 3C, and 8 of Chapter 143 of the General Statutes, together with rules
12 and procedures adopted under those Articles concerning procurement, contracting, and contract
13 review.

14 (g) Nothing in this section prevents the Commissioner from negotiating a mutually
15 acceptable agreement with any pharmacy benefits manager as to any civil penalty or restitution.

16 (h) Unless otherwise specifically provided for, all administrative proceedings under this
17 Article are governed by Chapter 150B of the General Statutes. Appeals of the Commissioner's
18 orders under this section shall be governed by G.S. 58-2-75.

19 **"§ 58-56A-45. Rules.**

20 The Commissioner shall adopt rules to implement the provisions of this Article.

21 **"§ 58-56A-50. Contracts with 340B covered entities.**

22 (a) A contract entered into between a pharmacy benefits manager and a 340B covered
23 entity's pharmacy or between a pharmacy benefits manager and a 340B contract pharmacy shall
24 not do any of the following:

25 (1) Restrict access to a pharmacy network or adjust 340B drug reimbursement
26 rates based on whether a pharmacy dispenses drugs under the 340B drug
27 discount program.

28 (2) Assess any additional, or vary the amount of any, fees, chargebacks, or other
29 adjustments on the basis of a drug being dispensed under the 340B drug
30 discount program or a pharmacy's status as a 340B covered entity or a 340B
31 contract pharmacy. This section does not prevent adjustments to correct errors
32 or overpayments resulting from an adjudicated claim.

33 (b) No pharmacy benefits manager making payments pursuant to a health benefit plan
34 shall discriminate against a 340B covered entity or a 340B contract pharmacy in a manner that
35 prevents or interferes with an enrollee's choice to receive a prescription drug from an in-network
36 340B covered entity or an in-network 340B contract pharmacy.

37 (c) The provisions of G.S. 58-51-37 shall apply to pharmacy benefits managers with
38 respect to 340B covered entities and 340B contract pharmacies.

39 (d) Any provision of a contract entered into between a pharmacy benefits manager and a
40 340B covered entity or 340B contract pharmacy that is contrary to this section is unenforceable."

41 **SECTION 2.** G.S. 58-2-40(5) reads as rewritten:

42 "(5) Report in detail to the Attorney General any violations of the laws relative to
43 pharmacy benefits managers, insurance companies, associations, orders and
44 bureaus or the business of insurance; and the Commissioner may institute civil
45 actions or criminal prosecutions either by the Attorney General or another
46 attorney whom the Attorney General may select, for any violation of the
47 provisions of Articles 1 through 64 of this Chapter."

48 **SECTION 3.** G.S. 58-56-2 reads as rewritten:

49 **"§ 58-56-2. Definitions.**

50 The following definitions apply in this Article:

51 ...

(5) Third party administrator. A person who directly or indirectly solicits or effects coverage of, underwrites, collects charges or premiums from, or adjusts or settles claims on residents of this State, or residents of another state from offices in this State, in connection with life or health insurance or annuities, except any of the following:

...

m. A pharmacy benefits manager licensed under Article 56A of this Chapter.

...."

SECTION 4. G.S. 58-51-37 reads as rewritten:

"§ 58-51-37. Pharmacy of choice.

(a) This section shall apply to all health benefit plans providing pharmaceutical services benefits, including prescription drugs, to any resident of North Carolina. This section shall also apply to insurance companies and health maintenance organizations that provide or administer coverages and benefits for prescription drugs. This section shall apply to pharmacy benefits managers with respect to 340B covered entities and 340B contract pharmacies, as defined in G.S. 58-56A-1. This section shall not apply to any entity that has its own facility, employs or contracts with physicians, pharmacists, nurses, and other health care personnel, and that dispenses prescription drugs from its own pharmacy to its employees and to enrollees of its health benefit plan; provided, however, this section shall apply to an entity otherwise excluded that contracts with an outside pharmacy or group of pharmacies to provide prescription drugs and services. This section shall not apply to any federal program, clinical trial program, hospital or other health care facility licensed pursuant to Chapter 131E or Chapter 122C of the General Statutes, when dispensing prescription drugs to its patients.

...."

SECTION 5. No later than December 1, 2021, the Department of Insurance shall convene a stakeholder workgroup to study and recommend a single, unified process to accredit specialty pharmacies in the State. The workgroup shall examine at least the regulatory, administrative, and financial challenges facing those who wish to gain specialty pharmacy status. The workgroup shall be composed of at least two representatives from each of the following: independent pharmacies, pharmacy service administrative organizations, pharmacy benefits managers, and insurers who offer health benefit plans. The workgroup shall meet at least three times and shall report its findings and recommendations to the Joint Legislative Oversight Committee on Health and Human Services, the Senate Health Care Committee, and the House Health Committee no later than May 15, 2022.

SECTION 6. This act becomes effective October 1, 2021, and applies to any contracts entered into, renewed, or amended on or after that date.