CHAPTER _____

AN ACT concerning

Health Insurance and Pharmacy Benefits Managers – Cost Pricing and Reimbursement

FOR the purpose of authorizing a pharmacist or a pharmacy to decline to dispense a prescription drug or provide a pharmacy service to a certain member if the amount reimbursed by a certain insurer, nonprofit health service plan, or health maintenance organization is less than a certain acquisition cost; providing that certain provisions of this Act apply in a certain manner to contracts between pharmacy benefits managers that contract with managed care organizations; prohibiting a certain contract or amendment to a certain contract from becoming effective except under certain circumstances; clarifying that certain provisions of law apply to certain appeals; providing that a certain process required to be included in certain contracts must include a requirement that a pharmacy benefits manager provide a certain mathematical calculation; requiring the Commissioner to take certain actions if a designee of the contracted pharmacy files a complaint; requiring a pharmacy benefits manager to provide certain information to the Commissioner for a certain purpose under certain circumstances; requiring that each contract between a pharmacy benefits manager and a contracted pharmacy include a certain process to appeal, investigate, and resolve disputes regarding cost pricing and reimbursement, rather than only maximum allowable cost pricing; requiring that the appeals process include a requirement that a pharmacy benefits manager provide a certain formulary under certain circumstances; certain information:

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.
[Brackets] indicate matter deleted from existing law.
Underlining indicates amendments to bill.
Strike out indicates matter stricken from the bill by amendment or deleted from the law by amendment.
repealing the authority of a pharmacy benefits manager to retroactively deny or modify reimbursement to a pharmacy or pharmacist for an approved claim that caused certain monetary loss; prohibiting pharmacy benefits managers and certain purchasers from directly or indirectly charging a contracted pharmacy, or holding a contracted pharmacy responsible for, fees or reimbursements related to the adjudication of certain claims; providing that certain actions are a violation of certain provisions of law; defining certain terms; making conforming and technical changes; making this Act an emergency measure; providing for the application of certain provisions of this Act; and generally relating to cost pricing and reimbursement of prescription drugs.

BY adding to
Article – Health – General
Section 15–102.3(g)
Annotated Code of Maryland
(2015 Replacement Volume and 2018 Supplement)

BY repealing and reenacting, without amendments,
Article – Insurance
Section 15–1601(a)
Annotated Code of Maryland
(2017 Replacement Volume and 2018 Supplement)

BY adding to
Article – Insurance
Section 15–1012 and 15–1628.2 15–1601(c–1), (c–2), and (h–1), 15–1628.2, and 15–1628.3
Annotated Code of Maryland
(2017 Replacement Volume and 2018 Supplement)

BY repealing
Article – Insurance
Section 15–1628.1(f) through (i)
Annotated Code of Maryland
(2017 Replacement Volume and 2018 Supplement)

BY repealing and reenacting, with amendments,
Article – Insurance
Section 15–1631 15–1628, 15–1628.1, 15–1631, and 15–1642
Annotated Code of Maryland
(2017 Replacement Volume and 2018 Supplement)

SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, That the Laws of Maryland read as follows:

Article – Health – General
15–102.3.

(g) The provisions of § 15–1628.3 of the Insurance Article apply to pharmacy benefits managers that contract with managed care organizations in the same manner as they apply to a pharmacy benefits managers that contract with carriers.

Article – Insurance

15–1012.

(A) In this section, “member” means an individual entitled to health care benefits for prescription drugs or pharmacy services under a policy or contract issued or delivered in the State by an entity subject to this section.

(B) (1) This section applies to:

   (i) insurers and nonprofit health service plans that provide coverage for prescription drugs and pharmacy services under health insurance policies or contracts that are issued or delivered in the State; and

   (ii) health maintenance organizations that provide coverage for prescription drugs and pharmacy services under contracts that are issued or delivered in the State.

(2) An insurer, a nonprofit health service plan, or a health maintenance organization that provides coverage for prescription drugs and pharmacy services through a pharmacy benefits manager is subject to the requirements of this section.

(C) If the amount reimbursed by an entity subject to this section for a prescription drug or pharmacy service is less than the pharmacy acquisition cost for the same prescription drug or pharmacy service, the pharmacist or pharmacy may decline to dispense the prescription drug or provide the pharmacy service to a member.

15–1601.

(a) In this subtitle the following words have the meanings indicated.

(C–1) “Compensation program” means a program, policy, or process through which sources and pricing information are used by a pharmacy
BENEFITS MANAGER TO DETERMINE THE TERMS OF PAYMENT AS STATED IN A PARTICIPATING PHARMACY CONTRACT.

(C–2) “CONTRACTED PHARMACY” MEANS A PHARMACY THAT PARTICIPATES IN THE NETWORK OF A PHARMACY BENEFITS MANAGER THROUGH A CONTRACT WITH:

(I) THE PHARMACY BENEFITS MANAGER; OR

(II) A PHARMACY SERVICES ADMINISTRATION ORGANIZATION OR A GROUP PURCHASING ORGANIZATION.

(H–1) “PARTICIPATING PHARMACY CONTRACT” MEANS A CONTRACT FILED WITH THE COMMISSIONER IN ACCORDANCE WITH § 15–1628(B) OF THIS SUBTITLE.

(A) At the time of entering into a contract with a pharmacy or a pharmacist, and at least 30 working days before any contract change, a pharmacy benefits manager shall disclose to the pharmacy or pharmacist:

(1) the applicable terms, conditions, and reimbursement rates;

(2) the process and procedures for verifying pharmacy benefits and beneficiary eligibility;

(3) the dispute resolution and audit appeals process; and

(4) the process and procedures for verifying the prescription drugs included on the formularies used by the pharmacy benefits manager.

(B) (1) A CONTRACT OR AN AMENDMENT TO A CONTRACT BETWEEN A PHARMACY BENEFITS MANAGER, A PHARMACY SERVICES ADMINISTRATION ORGANIZATION, OR A GROUP PURCHASING ORGANIZATION AND A PHARMACY MAY NOT BECOME EFFECTIVE UNLESS:

(I) AT LEAST 30 DAYS BEFORE THE CONTRACT OR AMENDMENT IS TO BECOME EFFECTIVE, THE PHARMACY BENEFITS MANAGER, PHARMACY SERVICES ADMINISTRATION ORGANIZATION, OR GROUP PURCHASING ORGANIZATION FILES THE CONTRACT OR AMENDMENT WITH THE COMMISSIONER IN THE FORM REQUIRED BY THE COMMISSIONER; AND

(II) THE COMMISSIONER DOES NOT DISAPPROVE THE FILING WITHIN 30 DAYS AFTER THE CONTRACT OR AMENDMENT IS FILED.
(2) The Commissioner shall adopt regulations to establish the circumstances under which the Commissioner may disapprove a contract.

15–1628.1.

(a) (1) In this section the following words have the meanings indicated.

(2) “Contracted pharmacy” means a pharmacy that participates in the network of a pharmacy benefits manager through a contract with:

(i) the pharmacy benefits manager; or

(ii) a pharmacy services administration organization or a group purchasing organization.

(3) “Drug shortage list” means a list of drug products listed on the federal Food and Drug Administration’s Drug Shortages website.

(4) (i) “Maximum allowable cost” means the maximum amount that a pharmacy benefits manager or a purchaser will reimburse a contracted pharmacy for the cost of a multisource generic drug, a medical product, or a device.

(ii) “Maximum allowable cost” does not include dispensing fees.

(5) “Maximum allowable cost list” means a list of multisource generic drugs, medical products, and devices for which a maximum allowable cost has been established by a pharmacy benefits manager or a purchaser.

(b) In each Participating Pharmacy contract [between a pharmacy benefits manager and a contracted pharmacy], the pharmacy benefits manager shall include the sources used to determine maximum allowable cost pricing.

(c) A pharmacy benefits manager shall:

(1) update its pricing information at least every 7 days;

(2) establish a reasonable process by which a contracted pharmacy has access to the current and applicable maximum allowable cost price lists in an electronic format as updated in accordance with the requirements of this section; and

(3) immediately after a pricing information update under item (1) of this subsection, use the updated pricing information in calculating the payments made to all contracted pharmacies.
(d) (1) A pharmacy benefits manager shall maintain a procedure to eliminate products from the list of drugs subject to maximum allowable cost pricing as necessary to:

(i) remain consistent with pricing changes;

(ii) remove from the list drugs that no longer meet the requirements of subsection (e) of this section; and

(iii) reflect the current availability of drugs in the marketplace.

(2) A product on the maximum allowable cost list shall be eliminated from the list by the pharmacy benefits manager within 7 days after the pharmacy benefits manager knows of a change in the availability of the product.

(e) Before placing a prescription drug on a maximum allowable cost list, a pharmacy benefits manager shall ensure that:

(1) the drug is listed as “A” or “B” rated in the most recent version of the U.S. Food and Drug Administration’s approved drug products with therapeutic equivalence evaluations, also known as the Orange Book, or has an “NR” or “NA” rating or similar rating by a nationally recognized reference;

(2) (i) if a drug is manufactured by more than one manufacturer, the drug is generally available for purchase by contracted pharmacies, including contracted retail pharmacies, in the State from a wholesale distributor with a permit in the State; or

(ii) if a drug is manufactured by only one manufacturer, the drug is generally available for purchase by contracted pharmacies, including contracted retail pharmacies, in the State from at least two wholesale distributors with a permit in the State; and

(3) the drug is not obsolete, temporarily unavailable, or listed on a drug shortage list as currently in shortage.

(f) Each FOR DISPUTES REGARDING MAXIMUM ALLOWABLE COST PRICING, EACH PARTICIPATING PHARMACY contract between a pharmacy benefits manager and a contracted pharmacy must include a process to appeal, investigate, and resolve disputes regarding maximum allowable cost pricing that includes:

(1) a requirement that an appeal be filed by the contract pharmacy no later than 21 days after the date of the initial adjudicated claim;

(2) a requirement that, within 21 days after the date the appeal is filed, the pharmacy benefits manager investigate and resolve the appeal and report to the contracted pharmacy on the pharmacy benefits manager’s determination on the appeal;
(3) a requirement that a pharmacy benefits manager make available on its website information about the appeal process, including:

(i) a telephone number at which the contracted pharmacy may directly contact the department or office responsible for processing appeals for the pharmacy benefits manager to speak to an individual or leave a message for an individual who is responsible for processing appeals;

(ii) an e-mail address of the department or office responsible for processing appeals to which an individual who is responsible for processing appeals has access; and

(iii) a notice indicating that the individual responsible for processing appeals shall return a call or an e-mail made by a contracted pharmacy to the individual within 3 business days or less of receiving the call or e-mail;

(4) a requirement that a pharmacy benefits manager provide:

(i) a reason for any appeal denial; and

(ii) the national drug code of a drug and the name of the wholesale distributor from which the drug was available on the date the claim was adjudicated at a price at or below the maximum allowable cost determined by the pharmacy benefits manager; and

(III) THE MATHEMATICAL CALCULATION USED TO DETERMINE THE MAXIMUM ALLOWABLE COST; AND

(5) if an appeal is upheld, a requirement that a pharmacy benefits manager:

(i) for the appealing pharmacy:

1. adjust the maximum allowable cost for the drug as of the date of the original claim for payment; and

2. without requiring the appealing pharmacy to reverse and rebill the claims, provide reimbursement for the claim and any subsequent and similar claims under similarly applicable contracts with the pharmacy benefits manager:

   A. for the original claim, in the first remittance to the pharmacy after the date the appeal was determined; and

   B. for subsequent and similar claims under similarly applicable contracts, in the second remittance to the pharmacy after the date the appeal was determined; and
(ii) for a similarly situated contracted pharmacy in the State:

1. adjust the maximum allowable cost for the drug as of the
date the appeal was determined; and

2. provide notice to the pharmacy or pharmacy’s contracted
agent that:

   A. an appeal has been upheld; and

   B. without filing a separate appeal, the pharmacy or the
pharmacy’s contracted agent may reverse and rebill a similar claim.

(g) A pharmacy benefits manager may not retaliate against a contracted
pharmacy for exercising its right to appeal under this section or filing a complaint with the
Commissioner under this subsection.

(h) A pharmacy benefits manager may not charge a contracted pharmacy a fee
related to the readjudication of a claim or claims resulting from carrying out the
requirement of a contract specified in subsection (f)(5) of this section or the upholding of an
appeal under subsection (i) of this section.

(i) (1) If a pharmacy benefits manager denies an appeal and a contracted
pharmacy OR A DESIGNEE OF THE CONTRACTED PHARMACY files a complaint with the
Commissioner, the Commissioner shall:

   (i) review the compensation program of the pharmacy benefits
manager to ensure that the reimbursement for pharmacy benefits management services
paid to the pharmacist or a pharmacy complies with this subtitle and the terms of the
PARTICIPATING PHARMACY contract; and

   (ii) based on a determination made by the Commissioner under item
(i) of this paragraph, dismiss the appeal or uphold the appeal and order the pharmacy
benefits manager to pay the claim or claims in accordance with the Commissioner’s
findings.

(2) ON REQUEST, THE PHARMACY BENEFITS MANAGER SHALL
provide to the Commissioner on request all mathematical
calculations, accounts, records, documents, files, logs,
correspondence, or other information necessary to complete the
Commissioner’s review under paragraph (1) of this subsection.

(2) (3) All pricing information and data collected by the Commissioner
during a review required by paragraph (1) of this subsection:

   (i) is considered to be confidential and proprietary information; and
(ii) is not subject to disclosure under the Public Information Act.

15–1628.2.

(A) In this section, “Contracted Pharmacy” means a pharmacy that participates in the network of a pharmacy benefits manager through a contract with:

1. The pharmacy benefits manager; or

2. A pharmacy services administration organization or a group purchasing organization.

(B) (A) Each for disputes regarding cost pricing and reimbursement under a participating pharmacy contract, each participating pharmacy contract between a pharmacy benefits manager and a contracted pharmacy must include a process to appeal, investigate, and resolve disputes regarding cost pricing and reimbursement that includes:

(1) A requirement that an appeal be filed by the contract pharmacy not later than 21 days after the date of the initial adjudicated claim:

(I) the date a direct or indirect remuneration fee is charged; or

(II) another date as determined by the Commissioner;

(2) A requirement that, within 21 days after the date the appeal is filed, the pharmacy benefits manager investigate and resolve the appeal and report to the contracted pharmacy on the pharmacy benefits manager’s determination on the appeal;

(3) (2) A requirement that a pharmacy benefits manager make available on its website information about the appeal process, including:

(I) a telephone number at which the contracted pharmacy may directly contact the department or office responsible for processing appeals for the pharmacy benefits manager to speak to an individual or leave a message for an individual who is responsible for processing appeals;
(II) an e-mail address of the department or office responsible for processing appeals to which an individual who is responsible for processing appeals has access; and

(III) a notice indicating that the individual responsible for processing appeals shall return a call or an e-mail made by a contracted pharmacy to the individual within 3 business days or less after receiving the call or e-mail;

(4) (3) a requirement that a pharmacy benefits manager provide:

(1) a reason for any appeal denial; and

(II) 1. the national drug code of a drug and the name of the wholesale distributor from which the drug was available on the date the claim was adjudicated at a price at or below the maximum allowable cost determined by the pharmacy benefits manager; or

2. (II) if the pharmacy benefits manager does not use maximum allowable cost in determining the amount of reimbursement to a pharmacy or pharmacist, the formulary mathematical calculation used to determine the amount of reimbursement; and

(5) (4) if an appeal is upheld, a requirement that a pharmacy benefits manager:

(1) for the appealing pharmacy:

1. adjust the cost or reimbursement for the drug as of the date of the original claim for payment; and

2. without requiring the appealing pharmacy to reverse and rebill the claims, provide reimbursement for the claim and any subsequent and similar claims under similarly applicable contracts with the pharmacy benefits manager:

A. for the original claim, in the first remittance to the pharmacy after the date the appeal was determined; and
B. FOR SUBSEQUENT AND SIMILAR CLAIMS UNDER SIMILARLY APPLICABLE CONTRACTS, IN THE SECOND REMITTANCE TO THE PHARMACY AFTER THE DATE THE APPEAL WAS DETERMINED; AND

(II) FOR A SIMILARLY SITUATED CONTRACTED PHARMACY IN THE STATE:

1. ADJUST THE COST OR REIMBURSEMENT FOR THE DRUG AS OF THE DATE THE APPEAL WAS DETERMINED; AND

(1) MAKE ADJUSTMENTS AS NECESSARY TO COMPLY WITH THE COMPENSATION PROGRAM AS STATED IN THE PARTICIPATING PHARMACY CONTRACT AS OF THE DATE THE APPEAL WAS DETERMINED; AND

2. (II) PROVIDE NOTICE TO THE PHARMACY OR PHARMACY’S CONTRACTED AGENT THAT:

A. AN APPEAL HAS BEEN UPHeld; AND

B. WITHOUT FILING A SEPARATE APPEAL, THE PHARMACY OR THE PHARMACY’S CONTRACTED AGENT MAY REVERSE AND REBILL A SIMILAR CLAIM.

(C) A PHARMACY BENEFITS MANAGER MAY NOT RETALIATE AGAINST A CONTRACTED PHARMACY FOR EXERCISING ITS RIGHT TO APPEAL UNDER THIS SECTION OR FILING A COMPLAINT WITH THE COMMISSIONER UNDER THIS SECTION.

(D) A PHARMACY BENEFITS MANAGER MAY NOT CHARGE A CONTRACTED PHARMACY A FEE RELATED TO THE READJUDICATION OF A CLAIM OR CLAIMS RESULTING FROM CARRYING OUT THE REQUIREMENT OF A CONTRACT SPECIFIED IN SUBSECTION (B)(5) OF THIS SECTION OR THE UPHOLDING OF AN APPEAL UNDER SUBSECTION (E) OF THIS SECTION.

(E) (1) IF A PHARMACY BENEFITS MANAGER DENIES AN APPEAL AND A CONTRACTED PHARMACY OR A DESIGNEE OF THE CONTRACTED PHARMACY FILES A COMPLAINT WITH THE COMMISSIONER, THE COMMISSIONER SHALL:

(i) REVIEW THE COMPENSATION PROGRAM OF THE PHARMACY BENEFITS MANAGER TO ENSURE THAT THE REIMBURSEMENT FOR PHARMACY BENEFITS MANAGEMENT SERVICES PAID TO THE PHARMACIST OR A PHARMACY COMPLIES WITH THIS SUBTITLE AND THE TERMS OF THE PARTICIPATING PHARMACY CONTRACT; AND
(II) based on a determination made by the Commissioner under item (i) of this paragraph, dismiss the appeal or uphold the appeal and order the pharmacy benefits manager to pay the claim or claims in accordance with the Commissioner’s findings.

(2) On request, the pharmacy benefits manager shall provide to the Commissioner on request all mathematical calculations, accounts, records, documents, files, logs, correspondence, or other information necessary to complete the Commissioner’s review.

(2)(3) All pricing information and data collected by the Commissioner during a review required by paragraph (1) of this subsection:

(i) is considered to be confidential and proprietary information; and

(ii) is not subject to disclosure under the Public Information Act.

15–1628.3.

A pharmacy benefits manager or a purchaser may not directly or indirectly charge a contracted pharmacy, or hold a contracted pharmacy responsible for, a fee or performance–based reimbursement related to the adjudication of a claim or an incentive program that is not:

(1) specifically enumerated by the pharmacy benefits manager or purchaser at the time of claim processing; or

(2) reported on the initial remittance advice of an adjudicated claim.

15–1631.

Except for an overpayment as defined in § 15–1629(h) of this subtitle, if a claim has been approved by a pharmacy benefits manager through adjudication, the pharmacy benefits manager may not retroactively deny or modify reimbursement to a pharmacy or pharmacist for the approved claim unless:

(1) the claim was fraudulent;
(2) the pharmacy or pharmacist had been reimbursed for the claim previously; OR

(3) the services reimbursed were not rendered by the pharmacy or pharmacist; or

(4) subject to § 15–1629(h)(2) of this part, the claim otherwise caused monetary loss to the pharmacy benefits manager, provided that the pharmacy benefits manager allowed the pharmacy a reasonable opportunity to remedy the cause of the monetary loss.

15–1642.

(A) IT IS A VIOLATION OF THIS SUBTITLE FOR A PHARMACY BENEFITS MANAGER TO:

(1) MISREPRESENT PERTINENT FACTS OR POLICY PROVISIONS THAT RELATE TO A CLAIM OR THE COMPENSATION PROGRAM AT ISSUE IN A COMPLAINT OR AN APPEAL OF A DECISION REGARDING A COMPLAINT;

(2) REFUSE TO PAY A CLAIM FOR AN ARBITRARY OR CAPRICIOUS REASON BASED ON ALL AVAILABLE INFORMATION;

(3) FAIL TO SETTLE A CLAIM OR DISPUTE PROMPTLY WHENEVER LIABILITY IS REASONABLY CLEAR UNDER ONE PART OF A POLICY OR CONTRACT, IN ORDER TO INFLUENCE SETTLEMENTS UNDER OTHER PARTS OF THE POLICY OR CONTRACT; OR

(4) FAIL TO ACT IN GOOD FAITH.

(B) IT IS A VIOLATION OF THIS SUBTITLE FOR A PHARMACY BENEFITS MANAGER, WHEN COMMITTED AT A FREQUENCY TO INDICATE A GENERAL BUSINESS PRACTICE, TO:

(1) MISREPRESENT PERTINENT FACTS OR POLICY PROVISIONS THAT RELATE TO A CLAIM, THE COMPENSATION PROGRAM, OR THE COVERAGE AT ISSUE IN A COMPLAINT OR AN APPEAL OF A DECISION REGARDING A COMPLAINT;

(2) FAIL TO MAKE A PROMPT, FAIR, AND EQUITABLE GOOD–FAITH ATTEMPT TO SETTLE CLAIMS FOR WHICH LIABILITY HAS BECOME REASONABLY CLEAR;

(3) FAIL TO SETTLE A CLAIM PROMPTLY WHENEVER LIABILITY IS REASONABLY CLEAR UNDER ONE PART OF A POLICY OR CONTRACT, IN ORDER TO INFLUENCE SETTLEMENTS UNDER OTHER PARTS OF THE POLICY OR CONTRACT; OR
(4) REFUSE TO PAY A CLAIM FOR AN ARBITRARY OR CAPRIOUS REASON BASED ON ALL AVAILABLE INFORMATION.

(a) If the Commissioner determines that a pharmacy benefits manager has violated any provision of this subtitle or any regulation adopted under this subtitle, the Commissioner may issue an order that requires the pharmacy benefits manager to:

1. cease and desist from the identified violation and further similar violations;
2. take specific affirmative action to correct the violation;
3. make restitution of money, property, or other assets to a person that has suffered financial injury because of the violation; or
4. pay a fine in an amount determined by the Commissioner.

(b) An order of the Commissioner issued under this section may be served on a pharmacy benefits manager that is registered under Part II of this subtitle in the manner provided in § 2-204 of this article.

1. An order of the Commissioner issued under this section may be served on a pharmacy benefits manager that is not registered under Part II of this subtitle in the manner provided in § 4-206 or § 4-207 of this article for service on an unauthorized insurer that does an act of insurance business in the State.

2. A request for a hearing on any order issued under this section does not stay that portion of the order that requires the pharmacy benefits manager to cease and desist from conduct identified in the order.

3. The Commissioner may file a petition in the circuit court of any county to enforce an order issued under this section, whether or not a hearing has been requested or, if requested, whether or not a hearing has been held.

4. If the Commissioner prevails in an action brought under this section, the Commissioner may recover, for the use of the State, reasonable attorney’s fees and the costs of the action.

(c) In addition to any other enforcement action taken by the Commissioner under this section, the Commissioner may impose a civil penalty not exceeding $10,000 for each violation of this subtitle.

(d) The Commissioner may adopt regulations:

1. to carry out this subtitle; and
(2) to establish a complaint process to address grievances and appeals brought in accordance with this subtitle.

[(e) (G)] This section does not limit any other regulatory authority of the Commissioner under this article.

SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect October 1, 2019.

SECTION 2. AND BE IT FURTHER ENACTED, That this Act is an emergency measure, is necessary for the immediate preservation of the public health or safety, has been passed by a yea and nay vote supported by three–fifths of all the members elected to each of the two Houses of the General Assembly, and shall take effect from the date it is enacted.

Approved:

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Governor.

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Speaker of the House of Delegates.

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President of the Senate.