

REPORT 6 OF THE COUNCIL ON MEDICAL SERVICE (A-24)
Economics of Prescription Medication Prior Authorization
(Resolution 725-A-23)
(Reference Committee G)

EXECUTIVE SUMMARY

At the 2023 Annual Meeting, the House of Delegates referred Resolution 725, which asked that the American Medical Association (AMA) work with the federal government and third-party payers and surrogates to include economic information on medications that are denied prior authorization.

The Council reviewed information regarding factors that contribute to the current state of prior authorization: formularies, rebates, and prescription drug pricing. Each of these factors contain layers of confusion and lack transparency. Not only are these factors opaque and complicated individually, but each interacts with the evolution of prior authorization. To better understand prior authorization denials, the Council examined information on the history of prior authorization and its current state. The Council found that denials are often issued by payers in a manner that is confusing and inconsistent for both physicians and patients. The Council also reviewed potential solutions to the problem, namely the utilization of real-time prescription benefit tools (RTBTs). These tools allow physicians to access patient coverage information at the time of prescribing, presenting an opportunity to improve the care delivery process and workflow. The current prior authorization system relies on communicating decisions after the prescription has been issued, often leading to care delays and adherence issues. Alternatively, RTBTs present coverage information prior to the prescription being written, allowing prescribers to identify care delivery hurdles earlier and avoiding unexpected prior authorization related delays.

Based on its review, the Council recommends the adoption of new AMA policy that outlines the basic requirements for prior authorization denial letters: a detailed explanation of denial reasoning, access to policies/rules cited as part of the denial, approved alternatives, and what is needed to approve the original prescription. Additionally, the Council recommends the amendment of current RTBT policy, to ensure alignment between patient and physician systems, that alternative prescriptions are offered, and that coverage information is honored by payers. Finally, the Council recommends the reaffirmation of a number of current policies to ensure that Pharmacy Benefit Managers (PBMs) are regulated, formulary data is available to physicians in real-time, that PBM actions do not erode the patient-physician relationship, and that prior authorization is not abused.

REPORT OF THE COUNCIL ON MEDICAL SERVICE

CMS Report 6-A-24

Subject: Economics of Prescription Medication Prior Authorization
(Resolution 725-A-23)

Presented by: Sheila Rege, MD Chair

Referred to: Reference Committee G

1 At the 2023 Annual Meeting, the House of Delegates referred Resolution 725-A-23, The
2 Economics of Prior Authorization, which was sponsored by the Organized Medical Staff Section.
3 This resolution asked;

4
5 That our American Medical Association advocate to the federal government that third party
6 payers and surrogates include economic information on the net costs of medication denied
7 prior authorization and, where applicable, comparative net costs of alternative approved or
8 suggested medications for each rejected prior authorization.
9

10 In response to the resolution, this report provides an overview of prior authorization and factors
11 that contribute to prescription medication prior authorization specifically, including formularies,
12 rebates, and drug pricing. The Council also explores that real-time benefit tools (RTBT) have the
13 potential to help solve this issue. The Council presents policy recommendations consistent with the
14 intent of Resolution 725-A-23.
15

16 BACKGROUND

17
18 The Council commends the sponsors of Resolution 725-A-23 for bringing forward this important
19 topic and believes that the spirit of the resolution has the potential to positively impact both
20 physicians and patients. Prior authorization is a complex and often frustrating process that
21 physicians face on a regular basis. While additional information in denial letters is warranted, as
22 suggested in the original resolution, the Council emphasizes that resources like RTBTs have the
23 potential to improve the prior authorization process faced by patients and physicians. These tools
24 allow physicians to access detailed information about the coverage of a prescription medication
25 before the prescription is written, which could reduce the number of denial letters, increase the
26 information accessible to physicians, and allow physicians to focus on patient care instead of
27 appeals. To fully understand prior authorization, its economic impact, and how RTBTs could assist
28 care delivery and workflow, it is necessary to understand some of the factors that contribute to the
29 complexity, such as formularies, rebates, and the lack of prescription drug price transparency.
30

31 Formularies, or the list of prescription drugs covered by a payer, are created via consultation with
32 experts, often supported or directed by pharmacy benefit managers (PBMs) and typically based on
33 clinical outcomes and the relative costs.^{1,2} Formularies are premised on reducing costs and
34 ensuring the appropriate use of pharmaceuticals.³ However, they often have negative impacts on
35 patients and physicians. Specifically, research has demonstrated that among studied formularies at
36 least half of all patient health care utilization and economic outcomes were not beneficial to

1 patients.³ Drugs on a formulary are typically divided into different tiers based on the drug’s price
 2 and the formulary designer’s preference. A drug’s tier position depends on a multitude of factors
 3 and can differ significantly between payers; however, one of the primary factors influencing any
 4 drug’s tier placement is the financial arrangement between the payer and the drug manufacturer for
 5 that drug. Unfortunately, a drug’s efficacy or its appropriateness for a particular patient, and its
 6 cost-effectiveness are often secondary considerations compared to the financial implications of the
 7 drug.

8
 9 Manufacturers offer rebates that are typically negotiated between PBMs and the drug manufacturer
 10 and are typically based on the list price of the drug. Along with prior authorization, rebates are
 11 generally used to encourage a payer to include favorable placement or inclusion on a formulary.⁴
 12 Increased rebates are sometimes used to incentivize placement on a preferred formulary tier.⁵
 13 Rebates are relied on heavily by PBMs and other payers to negotiate more lucrative deals, and to
 14 protect these financial positions, it is critical to PBMs and payers that the specific details of these
 15 arrangements remain confidential. Without access to more detailed information about rebates and
 16 other financial incentives, it is impossible for physicians to fully understand how much a drug truly
 17 costs.

18
 19 Payers often use prior authorization as a tool to discourage physicians from prescribing
 20 medications that are not on the payer’s preferred formulary tier. If a payer prefers that a physician
 21 prescribe one drug over another within the same drug class, the payer can simply apply a prior
 22 authorization requirement to the non-preferred medication. By placing prior authorization on non-
 23 preferred drugs, payers can drive utilization in their desired direction. It is often challenging for
 24 physicians to determine whether a prior authorization is required at all, let alone what the specific
 25 requirements are. The prior authorization process is often so opaque that physicians may not be
 26 notified that a prior authorization is required until they receive a denial letter from the payer, or the
 27 patient is turned away at the pharmacy counter, which can lead to delays and significant
 28 interruptions in ongoing care as well as disruptions to patient adherence. Although these payer
 29 coverage determination delays and/or issues are rarely the physician’s fault, patients may blame the
 30 physician, undermining the patient’s trust in the physician and potentially impacting the patient-
 31 physician relationship long-term.

32
 33 Physicians are often prescribing without access to drug cost and coverage information at the point
 34 of prescribing, making it almost impossible to avoid prescribing a drug that may be unaffordable
 35 under that specific patient’s plan. This can cause the physician to unknowingly prescribe a more
 36 expensive medication when a lower-cost and equally beneficial medication is available and can
 37 cause significant harm to patient outcomes. Specifically, more expensive medications have been
 38 linked to lower treatment adherence, and, in extreme cases, increases in morbidity and/or
 39 mortality.⁶ While there have been efforts from federal regulators and legislators to mitigate some of
 40 the negative impacts from medication prior authorization, the process remains opaque and
 41 complicated and, as a result, patients may not be able to readily access lower-cost alternative
 42 medications. Additionally, there is very little transparency from PBMs and payers regarding
 43 rebates, formulary makeup, and drug costs.⁶ Rebate information is considered proprietary data and
 44 as such is not accessible for scrutiny, making it incredibly difficult for any regulating body to have
 45 accurate data leading to challenges in effective regulation.

46
 47 **PRIOR AUTHORIZATION DENIALS**

48
 49 The roots of prior authorization can be traced back to the original Medicare and Medicaid
 50 legislation from the 1960s which introduced utilization review, or the process of verifying the need
 51 for treatment, often hospital stays, for a confirmed diagnosis.⁷ Over time, this process has expanded

1 to include the coverage of prescription medications and to what is now recognized as prior
2 authorization.⁷ When introduced, prior authorization was touted as a method to restrict significant
3 increases in the cost of prescription drugs, however this process has become one that is
4 burdensome for both patients and physicians.⁸ Prior authorization has resulted in several adverse
5 consequences ranging from increased administrative burden to patient inability to access necessary
6 medications.⁸ Additionally, the prior authorization process can undermine the patient-physician
7 relationship. Physicians and patients frequently have limited knowledge if prior authorization will
8 be required for a medication, hindering the ability for physicians to ensure affordable, timely
9 access to the medication they deem the most appropriate.⁹

10
11 Today, prior authorization has become pervasive throughout the health care system. A recent report
12 found that 99 percent of Medicare Advantage (MA) plans require prior authorization for at least
13 some services; most often for Part B drugs.¹⁰ Additionally, a study investigating MA plans found
14 that prior authorizations are submitted, on average, 1.5 times for each enrollee, adding up to
15 approximately 35 million requests in one year.¹¹ Of the submitted requests in MA plans this study
16 found that six percent, or approximately 2 million, were denied. However, this denial rate ranged
17 greatly among payers with some denial rates as high as double the average. Importantly, this study
18 found that only 11 percent of denied prior authorizations were appealed by either the patient or
19 provider. The vast majority of appeals were successful with 82 percent resulting in a full or partial
20 overturning of the denial. Similar to rates of denials, some payers saw much higher rates of appeal,
21 some reaching 20 percent of all denials. Further, for some payers, appeals were successful as much
22 as 94 percent of the time.¹¹ While this study is helpful in beginning to understand the rates of prior
23 authorization denials, the researchers did not have access to disaggregated data showing the service
24 type of prior authorization requests and were unable to access reasoning for each denial or
25 information on the timeliness of requests or appeals. Additionally, these statistics were only based
26 on MA plans; private plans were not included. It is important to note that physicians who are
27 forced to appeal prior authorization denials often face significant administrative costs. Physicians
28 and their offices are often required to hire additional staff and/or spend personal time managing
29 authorizations and appeals.

30
31 Legislators and regulators have introduced rules and regulations that are designed to minimize the
32 struggles that plague the prior authorization process. For example, a recent final regulation from
33 the Centers for Medicare & Medicaid Services (CMS) requires that as of January 1, 2027, payers,
34 including MA, Medicaid, Children's Health Insurance Program, and Qualified Health Plans on the
35 Federally Facilitated Exchange are required to maintain a prior authorization application
36 programming interface (API). This API must include information on covered items and services,
37 identification of documents required for prior authorization, be supportive of prior authorization
38 requests and payer responses, and communicate approvals, denials, or requests for additional
39 information.¹² Effective January 1, 2026, payers will be required to report metrics and follow a
40 stricter response timeline.¹³ While this rule will improve the regulation of prior authorization, it
41 does not extend to prescription drug prior authorization requests.

42
43 One of the biggest issues with prior authorization is the opaque and extensive denial process. Not
44 only is this a frustrating process for the patient looking to access treatment, but it is also
45 exasperating for physicians who are attempting to support their patients. When a denial letter is
46 sent out, it may not include effective information to understand and/or appeal the denial itself. For
47 example, physicians and patients may simply be informed that a medication has not been approved
48 without providing justification as to why the denial took place or an alternative treatment option.
49 Without clear information regarding the clinical rationale for the denial, patients and physicians are
50 often left to the frustrating process of guess work in attempting to find a treatment covered by the
51 patient's plan.

1 In order to improve the quantity and quality of information provided in denial letters, CMS has
2 implemented basic requirements for all Medicare health plans.¹⁴ These requirements, outlined in
3 CMS-10003-Notice of Denial of Medical Coverage or Payment form are in place for all medical
4 services and prescription drug denials. Specifically, in denial letters, plans must provide the
5 patient/physician with detailed information as to why the request was denied. Plans are required to
6 include a “specific and detailed” explanation for the denial, applicable coverage rules or plan
7 policies cited in the denial, and specific information as to what needs to be done to approve
8 coverage.¹⁴ These requirements ensure that the Medicare beneficiaries and their physicians are able
9 to have an understanding of the full scope of the denial via the notification letter.

10 11 REAL-TIME BENEFIT TOOL

12
13 To address the underlying concerns of Resolution 725-A-23, the Council worked to better
14 understand available data and what could feasibly be provided to physicians and patients. Not only
15 are there issues related to a lack of transparency due to prior authorization, at present, prior
16 authorization denial systems are not capable of producing specific net cost information on denials.
17 The Council believes that advocacy efforts supporting the betterment of alternative solutions, like
18 RTBTs, instead of the expansion of prior authorization systems better serve physicians and their
19 patients. One potential solution to the challenges faced due to prior authorization are RTBTs,
20 which allow patients and prescribers to access real-time information about coverage, including
21 formularies and benefit information at the point of prescribing.¹⁵ These tools simplify prescribing
22 with real-time information during an appointment. RTBTs allow prescribers to enter prescription
23 details, like type, amount, and intended pharmacy, and be informed, prior to writing the
24 prescription, of the cost and prior authorization requirements. RTBTs also allow physicians and
25 other prescribers to view alternative medications that may be lower cost to the patient and/or not
26 require prior authorization, thus allowing the prescriber to identify and prescribe the most
27 appropriate and accessible medication for a patient.¹⁶

28
29 RTBTs present an opportunity to improve the care delivery process by presenting prescribers with
30 critical prescription coverage and cost information at the point of prescribing. The current prior
31 authorization system relies heavily on relaying information to the patient/prescriber after a
32 prescription has been written and the patient has attempted to get that prescription filled. These
33 “post-prescription written denials,” usually delivered to prescribers via letters, often lead to
34 additional work for prescribers and their staff and result in immense administrative practice
35 burdens. In addition to increased work for physicians and their staff, the current prior authorization
36 process also often leads to patient care delays and adherence issues. RTBTs present all of the cost,
37 coverage, and other pertinent benefit information within the prescriber’s typical prescribing
38 workflow and allow the prescriber to not only identify prior authorization requirements prior to
39 writing the prescription, but also submit the prior authorization request directly to the payer sooner.

40
41 By providing information at the beginning of the prescribing process, RTBTs allow prescribers to
42 identify care delivery impediments earlier so they avoid any unexpected utilization management
43 delays. RTBTs have the potential to mitigate the impact of prior authorization denial letters by
44 informing prescribers of alternative, therapeutically equivalent medications that do not require
45 prior authorization at the point of care. RTBTs allow physicians to see which medications would be
46 covered and thus prior authorizations, and subsequent denial letters, should only be necessary if the
47 prescriber determines that the alternative, covered medication is not clinically appropriate. With
48 fewer denial letters, physicians can spend more time caring for patients and less time on appeals.

49

1 Current CMS regulation requires that all Medicare Part D plans provide at least one RTBT. In
 2 practice, for physicians and qualified providers to have access to RTBT information for all patients,
 3 they may need to support and integrate multiple RTBT and Electronic Health Records (EHR)
 4 systems. This is burdensome and complicated for all physicians to implement, and nearly
 5 impossible for smaller practices. Managing multiple systems is not only expensive and complex, it
 6 also may lead to confusion on RTBTs. In response to the complications that arose with the need to
 7 manage and support multiple RTBT and EHR systems, CMS has proposed a rule that would
 8 require Part D plans to implement a standardized system.¹⁷ This standard, the National Council for
 9 Prescription Drug Programs RTPB Standard Version 13 would allow for standardized formulary
 10 and benefit data in a manner that is reliable, detailed, and effectively integrated into systems.¹⁸ The
 11 AMA has been vocal in advocating for and supporting this proposed rule.¹⁹ Should the proposed
 12 rule be implemented, starting January 2027, this standardized system would allow for increasingly
 13 efficient physician access to clear information at the time of prescribing. Of note, this requirement
 14 would not extend to private insurers, however the requirement of this standard system by CMS
 15 could lead to future implementation in the private sector.

16
 17 **AMA ADVOCACY**

18
 19 The AMA’s extensive advocacy efforts work to address each of the systemic factors cited by
 20 Resolution 725-A-23, including prior authorization, formularies, rebates, prescription drug pricing
 21 transparency, and RTBTs. Regarding prior authorization, the AMA has an ongoing grassroots
 22 campaigns “[Fix Prior Auth](#)” to address the harm incurred by patients and physicians by prior
 23 authorization,²⁰ and [TruthinRx](#), which aims to educate patients, physicians, providers, and
 24 legislators about the issues that arise from the lack of price transparency.²¹ TruthinRx advocates for
 25 transparency from PBMs, payers, and manufacturers around formularies and rebates. The goals of
 26 these campaigns are to spread awareness, create legislative changes, and serve as an extensive
 27 resource for patients, physicians, and employers on these high priority issues.

28
 29 Additionally, the AMA conducts regular surveys to track and report the impact of prior
 30 authorization on patients and physicians. The survey includes questions aimed at better
 31 understanding the impact of prior authorization for generic medication. In addition to this work,
 32 AMA advocacy has commented on prior authorization via letters and testimony to state legislators,
 33 Congress, and federal agencies 35 times in 2023 alone and has already been active in advocating
 34 for these issues in 2024.

35
 36 AMA advocacy has commented on relevant transparency issues through 21 letters and testimonies
 37 to state legislators, Congress, and federal agencies in 2023. Finally, to support the implementation
 38 of RTBTs, AMA advocacy has sent 18 letters and testimonies in 2023 to Congress and federal
 39 agencies. Efforts have already been made, and continue to be made, in 2024 to advocate on these
 40 issues. Each of these factors contribute to the issues raised in Resolution 725-A-23 and are clearly
 41 on the AMA advocacy’s ongoing agenda.

42
 43 **AMA POLICY**

44
 45 Underscoring the extensive advocacy work on these issues is a robust body of AMA policy aimed
 46 at ensuring that prior authorization is monitored and minimized, PBMs are monitored and
 47 regulated, the process is transparent, and to support the implementation of adequate RTBT tools.

48
 49 Policy H-125.991 outlines the standards that both formulary systems and Pharmacy and
 50 Therapeutic Committees should meet. For example, this policy outlines that formulary systems
 51 should include oversight from organized medical staff. This policy is reinforced by similar

1 guidelines in Policy H-285.965, which, among other things, outlines that both physicians and
 2 patients should have access to clear information about a payer’s formulary and that these
 3 formularies should be created and maintained with the input of physicians. In addition to these
 4 policies dealing directly with the creation and maintenance of formularies, Policy H-110.981
 5 details advocacy efforts to ensure that PBMs and regulatory bodies make rebate and discount
 6 reports available to the public, ideally, assisting in disentangling the influence rebates have on the
 7 complex and opaque process that is formulary creation.

8
 9 AMA policy also deals directly with efforts to ensure that PBMs are monitored and that there is an
 10 increase in transparency regarding their operation. Specifically, Policy D-110.987 outlines the
 11 advocacy efforts that the AMA continues to implement to ensure that PBMs are required to
 12 increase transparency in their operating procedures and that they are adequately regulated on both a
 13 state and federal level. Additionally, Policy H-125.986 encourages physician engagement in
 14 reporting issues with PBMs and indicates efforts to increase PBM oversight and reduce PBM
 15 overreach in medical practice. Policy H-110.963 expands the coverage of regulation and
 16 monitoring to third-party PBMs. Each of these policies aim to implement adequate oversight of
 17 PBMs. Finally, Policies H-125.986 and D-120.933 outline the AMA’s support to ensure that
 18 PBMs’ actions do not impede or negatively impact the patient-physician relationship.

19
 20 In addition to AMA policy on contributing factors to prior authorization, the AMA has extensive
 21 policy on prior authorization and increasing physician access to real time prescribing information.
 22 Policy H-125.979 specifies AMA efforts to work with appropriate parties to ensure that physicians
 23 have access to real-time formulary data when prescribing a medication. Additionally, Policy
 24 H-120.919 outlines AMA efforts to support the implementation of RTBT tools that are helpful to
 25 prescribers and accurate at the time of prescribing. Finally, Policy H-320.945 outlines AMA
 26 opposition to prior authorization abuses and outlines the requirement for payers to report accurate
 27 statistics on approvals and denials.

28
 29 **DISCUSSION**

30
 31 Prior authorization is a tool that was initially introduced to save money and ensure that care given
 32 to patients was medically necessary. However, in the years since its introduction it has been
 33 overutilized and is now a burden for physicians as well as a barrier to patients accessing care. The
 34 opaqueness of both rebates and formularies contribute greatly to the confusion and subsequent
 35 frustration that results from denied prior authorization. The AMA continues to make significant
 36 efforts on multiple fronts to address this issue and ensure that prior authorization is fixed for
 37 patients and physicians.

38
 39 Resolution 725-A-23 asked that the AMA work to encourage the inclusion of economic
 40 information when prescription drugs are denied prior authorization. The Council believes that this
 41 concept would be beneficial to physicians and that alternative solutions, like RTBT tools, should be
 42 supported in order to mitigate the need for some prior authorizations. In the spirit of Resolution
 43 725-A-23, and to address the confusion that can arise from prior authorization denial letters, the
 44 Council recommends that a new policy be adopted to support working with appropriate parties to
 45 ensure that denial letters include information that is helpful to physicians and patients in
 46 understanding the full scope of denial. Such a policy will benefit ongoing and future AMA
 47 advocacy letters and testimony.

48
 49 The AMA has worked, and continues to work, extensively on ensuring that the burden of prior
 50 authorization is lessened for both physicians and patients. One aspect of this ongoing work has
 51 been rooted in policy outlining the AMA’s support for RTBT tools. This work advocates for

1 physicians to be able to access systems that are effective, efficient, and accurate. Accordingly, the
2 Council suggests amending Policy H-120.919 to better align the standards and language with CMS
3 policy, and to ensure that these tools provide a justification for the prior authorization requirement,
4 offer alternative(s), and that coverage determinations from the RTBT are honored.

5
6 Finally, the Council recommends that Policies H-110.963; Third-Party Pharmacy Benefit
7 Administrators; H-125.979; Private Health Insurance Formulary Transparency; H-320.945; Abuse
8 of Preauthorization Procedures; H-125.986 Pharmaceutical Benefit Management Companies; and
9 D-120.933 Pharmacy Benefit Managers Impact on Patients be reaffirmed. These policies outline
10 the AMA's efforts to ensure that all PBMs are monitored, regulated, and do not harm the
11 physician-patient relationship, that health insurers are required to be transparent about the creation
12 and maintenance of formularies, and that prior authorization is not abused by payers.

13 14 RECOMMENDATIONS

15
16 The Council on Medical Service recommends that the following be adopted in lieu of Resolution
17 725-A-23, and the remainder of the report be filed:

- 18
19 1. That our American Medical Association (AMA) support working with payers and
20 interested parties to ensure that prior authorization denial letters include at a minimum (1) a
21 detailed explanation of the denial reasoning, (2) a copy of or publicly accessible link to any
22 plan policy or coverage rules cited or used as part of the denial, and (3) what rationale or
23 additional documentation would need to be provided to approve the original prescription
24 and alternative options to the denied medication. (New HOD Policy)

- 25
26 2. That our AMA amend Policy H-120.919 to read as follows:

27
28 That our AMA will: (1) continue to support efforts to ~~publish~~ implement a Real-Time
29 Prescription Benefit (RTPB) Real-Time Benefit Tool (RTBT) standard that meets the
30 needs of all physicians and other prescribers, utilizing any electronic health record (EHR),
31 and prescribing on behalf of any insured patient; (2) support efforts to ensure that provider-
32 facing and patient facing RTBT systems align; and (3) advocate that all payers (i.e., public
33 and private prescription drug plans) be required to implement and keep up to date an RTPB
34 RTBT standard tool that integrates with all EHR vendors, and that any changes that must
35 be made to accomplish RTPB RTBT tool integration be accomplished with minimal
36 disruption to EHR usability and cost to physicians and hospitals; (4) advocate that RTBT
37 systems provide a justification for why prior authorization is required and include
38 approved/covered alternative prescription medications; and (35) develop and disseminate
39 educational materials that will empower physicians to be prepared to optimally utilize
40 RTPB tools RTBT and other health information technology tools that can be used to
41 enhance communications between physicians and pharmacists to reduce the incidence of
42 prescription abandonment; (6) advocate that payers honor coverage information that is
43 based on a RTBT at the time of prescription and that prior authorization approvals should
44 be valid for the duration of the prescribed/ordered treatment; and (7) continue to advocate
45 for the accuracy and reliability of data provided by RTBTs and for vendor neutrality to
46 ensure that it is supportive to physician efforts. (Modify Current HOD Policy)

- 47
48 3. That our AMA reaffirm Policy H-110.963, which addresses the regulation and monitoring
49 of third-party Pharmacy Benefit Managers (PBMs) in an effort to control prescription drug
50 pricing. (Reaffirm HOD Policy)

- 1 4. That our AMA reaffirm Policy H-125.979, which outlines advocacy efforts to ensure that
2 physicians have access to real-time formulary data when prescribing. (Reaffirm HOD
3 Policy)
4
- 5 5. That our AMA reaffirm Policy H-320.945, which details opposition to the abuse of prior
6 authorization and the requirement for payers to accurately report denials and approvals.
7 (Reaffirm HOD Policy)
8
- 9 6. That our AMA reaffirm Policy H-125.986, which outlines the AMA’s position that certain
10 actions from PBMs interfere with physician practice and may impact the patient-physician
11 relationship. (Reaffirm HOD Policy)
12
- 13 7. That our AMA reaffirm Policy D-120.933, which encourages the gathering of data to better
14 understand the impact that PBM actions may lead to an erosion of the patient-physician
15 relationship. (Reaffirm HOD Policy)

Fiscal Note: Less than \$500.

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**CMS Report Economics of Prior Authorization
Relevant AMA Policy**

Drug Formularies and Therapeutic Interchange (H-125.991)

It is the policy of the AMA:

- (1) That the following terms be defined as indicated:
 - a) **Formulary:** a compilation of drugs or drug products in a drug inventory list; open (unrestricted) formularies place no limits on which drugs are included whereas closed (restrictive) formularies allow only certain drugs on the list;
 - b) **Formulary system:** a method whereby the medical staff of an institution, working through the pharmacy and therapeutics committee, evaluates, appraises, and selects from among the numerous available drug entities and drug products those that are considered most useful in patient care;
 - c) **Pharmacy & Therapeutics (P&T) Committee:** an advisory committee of the medical staff that represents the official, organizational line of communication and liaison between the medical staff and the pharmacy department; its recommendations are subject to medical staff approval;
 - d) **Therapeutic alternates:** drug products with different chemical structures but which are of the same pharmacological and/or therapeutic class, and usually can be expected to have similar therapeutic effects and adverse reaction profiles when administered to patients in therapeutically equivalent doses;
 - e) **Therapeutic interchange:** authorized exchange of therapeutic alternates in accordance with previously established and approved written guidelines or protocols within a formulary system; and
 - f) **Therapeutic substitution:** the act of dispensing a therapeutic alternate for the drug product prescribed without prior authorization of the prescriber.

- (2) That our AMA reaffirms its opposition to therapeutic substitution (dispensing a therapeutic alternate without prior authorization) in any patient care setting.

- (3) That drug formulary systems, including the practice of therapeutic interchange, are acceptable in inpatient hospital and other institutional settings that have an organized medical staff and a functioning Pharmacy and Therapeutics (P&T) Committee, provided they satisfy the following standards:
 - (a) The formulary system must:
 - (i) have the concurrence of the organized medical staff;
 - (ii) openly provide detailed methods and criteria for the selection and objective evaluation of all available pharmaceuticals;
 - (iii) have policies for the development, maintenance, approval, and dissemination of the drug formulary and for continuous and comprehensive review of formulary drugs;
 - (iv) provide protocols for the procurement, storage, distribution, and safe use of formulary and non-formulary drug products;
 - (v) provide active surveillance mechanisms to regularly monitor both compliance with these standards and clinical outcomes where substitution has occurred, and to intercede where indicated;
 - (vi) have enough qualified medical staff, pharmacists, and other professionals to carry out these activities;

- (vii) provide a mechanism to inform the prescriber in a timely manner of any substitutions, and that allows the prescriber to override the system when necessary for an individual patient without inappropriate administrative burden;
 - (viii) provide a mechanism to assure that patients/guardians are informed of any change from an existing outpatient prescription to a formulary substitute while hospitalized, and whether the prior medication or the substitute should be continued upon discharge from the hospital;
 - (ix) include policies that state that practitioners will not be penalized for prescribing non-formulary drug products that are medically necessary; and
 - (x) be in compliance with applicable state and federal statutes and/or state medical board requirements.
- (b) The P&T Committee must:
- (i) objectively evaluate the medical usefulness and cost of all available pharmaceuticals (reliance on practice guidelines developed by physician organizations is encouraged);
 - (ii) recommend for the formulary those drug products which are the most useful and cost-effective in patient care;
 - (iii) conduct drug utilization review (DUR) activities;
 - (iv) provide pharmaceutical information and education to the organization's (e.g., hospital) staff;
 - (v) analyze adverse results of drug therapy;
 - (vi) make recommendations to ensure safe drug use and storage; and
 - (vii) provide protocols for the timely procurement of non-formulary drug products when prescribed by a physician for the individualized care of a specific patient, when that decision is based on sound scientific evidence or expert medical judgment.
- (c) The P&T Committee's recommendations must be approved by the medical staff;
- (d) Within the drug formulary system, the P & T Committee shall recommend, and the medical staff must approve, all drugs that are subject to therapeutic interchange, as well as all processes or protocols for informing individual prescribing physicians; and
- (e) The act of providing a therapeutic alternate that has not been recommended by the P&T Committee and approved by the medical staff is considered unauthorized therapeutic substitution and requires immediate prior consent by the prescriber, (i.e., authorization for a new prescription).
- (4) That drug formulary systems in any outpatient setting shall operate under a P&T Committee whose recommendations must have the approval of the medical staff or equivalent body and must meet standards comparable to those listed above. In addition:
- (a) That our AMA continues to insist that managed care and other health plans identify participating physicians as their "medical staff" and that they use such staff to oversee and approve plan formularies, as well as to oversee and participate on properly elected P&T Committees that develop and maintain plan formularies;
 - (b) That our AMA continues to insist that managed care and other health plans have well-defined processes for physicians to prescribe non-formulary drugs when medically indicated, that this process impose minimal administrative burdens, and that it include access to a formal appeals process for physicians and their patients; and

- (c) That our AMA strongly recommends that the switching of therapeutic alternates in patients with chronic diseases who are stabilized on a drug therapy regimen be discouraged.
- (5) That our AMA encourages mechanisms, such as incentive-based formularies with tiered co-pays, to allow greater choice and economic responsibility in drug selection but urges managed care plans and other third-party payers to not excessively shift costs to patients so they cannot afford necessary drug therapies. (BOT Rep. 45, I-93; Reaffirmed by Sub. Res. 501, A-95; Appended: BOT Rep. 7, I-99; Modified: Sub. Res. 524 and Reaffirmed: Res. 123, A-00; Reaffirmed: Res. 515, I-00; Reaffirmed: CMS Rep. 8, A-02; Reaffirmed: Res. 533, A-03; Modified: CMS Rep. 6, A-03; Modified: CSA Rep. 2, A-04; Reaffirmation I-04; Reaffirmed in lieu of Res. 535, A-05; Reaffirmed: BOT Action in response to referred for decision Res. 503, A-05; Reaffirmed: CMS Rep. 2, I-05; Reaffirmation A-06; Reaffirmation A-08; Reaffirmed: CMS Rep. 2, A-10; Reaffirmed: CMS Rep. 01, A-20)

The Impact of Pharmacy Benefit Managers on Patients and Physicians (D-110.987)

1. Our AMA supports the active regulation of pharmacy benefit managers (PBMs) under state departments of insurance.
2. Our AMA will develop model state legislation addressing the state regulation of PBMs, which shall include provisions to maximize the number of PBMs under state regulatory oversight.
3. Our AMA supports requiring the application of manufacturer rebates and pharmacy price concessions, including direct and indirect remuneration (DIR) fees, to drug prices at the point-of-sale.
4. Our AMA supports efforts to ensure that PBMs are subject to state and federal laws that prevent discrimination against patients, including those related to discriminatory benefit design and mental health and substance use disorder parity.
5. Our AMA supports improved transparency of PBM operations, including disclosing:
 - Utilization information;
 - Rebate and discount information;
 - Financial incentive information;
 - Pharmacy and therapeutics (P&T) committee information, including records describing why a medication is chosen for or removed in the P&T committee's formulary, whether P&T committee members have a financial or other conflict of interest, and decisions related to tiering, prior authorization, and step therapy;
 - Formulary information, specifically information as to whether certain drugs are preferred over others and patient cost-sharing responsibilities, made available to patients and to prescribers at the point-of-care in electronic health records;
 - Methodology and sources utilized to determine drug classification and multiple source generic pricing; and
 - Percentage of sole source contracts awarded annually.
6. Our AMA encourages increased transparency in how DIR fees are determined and calculated. (CMS Rep. 05, A-19; Reaffirmed: CMS Rep. 6, I-20)

Pharmaceutical Benefits Management Companies (H-125.986)

Our AMA:

- (1) encourages physicians to report to the Food and Drug Administration's (FDA) MedWatch reporting program any instances of adverse consequences (including therapeutic failures and adverse drug reactions) that have resulted from the switching of therapeutic alternates;
- (2) encourages the Federal Trade Commission (FTC) and the FDA to continue monitoring the relationships between pharmaceutical manufacturers and PBMs, especially with regard to

- manufacturers' influences on PBM drug formularies and drug product switching programs, and to take enforcement actions as appropriate;
- (3) pursues congressional action to end the inappropriate and unethical use of confidential patient information by pharmacy benefits management companies;
 - (4) states that certain actions/activities by pharmacy benefit managers and others constitute the practice of medicine without a license and interfere with appropriate medical care to our patients;
 - (5) encourages physicians to routinely review their patient's treatment regimens for appropriateness to ensure that they are based on sound science and represent safe and cost-effective medical care;
 - (6) supports efforts to ensure that reimbursement policies established by PBMs are based on medical need; these policies include, but are not limited to, prior authorization, formularies, and tiers for compounded medications; and
 - (7) encourages the FTC and FDA to monitor PBMs' policies for potential conflicts of interests and anti-trust violations, and to take appropriate enforcement actions should those policies advantage pharmacies in which the PBM holds an economic interest. (BOT Rep. 9, I-97; Appended: Res. 224, I-98; Appended: Res. 529, A-02; Reaffirmed: Res. 533A-03; Reaffirmation I-08; Reaffirmation A-10; Reaffirmed: Alt. Res. 806, I-17; Modified: Res. 242, A-18; Reaffirmed: CMS Rep. 08, A-19)

Third-Party Pharmacy Benefit Administrators (H-110.963)

1. Our AMA recommends that third-party pharmacy benefit administrators that contract to manage the specialty pharmacy portion of drug formularies be included in existing pharmacy benefit manager (PBM) regulatory frameworks and statutes, and be subject to the same licensing, registration, and transparency reporting requirements.
2. Our AMA will advocate that third-party pharmacy benefit administrators be included in future PBM oversight efforts at the state and federal levels. (Res. 820, I-22)

Private Health Insurance Formulary Transparency (H-125.979)

1. Our AMA will work with pharmacy benefit managers, health insurers, and pharmacists to enable physicians to receive accurate, real-time formulary data at the point of prescribing.
2. Our AMA supports legislation or regulation that ensures that private health insurance carriers declare which medications are available on their formularies by October 1 of the preceding year, that formulary information be specific as to generic versus trade name and include copay responsibilities, and that drugs may not be removed from the formulary nor moved to a higher cost tier within the policy term.
3. Our AMA will develop model legislation (a) requiring insurance companies to declare which drugs on their formulary will be covered under trade names versus generic, (b) requiring insurance carriers to make this information available to consumers by October 1 of each year and, (c) forbidding insurance carriers from making formulary deletions within the policy term.
4. Our AMA will promote the following insurer-pharmacy benefits manager - pharmacy (IPBMP) to physician procedural policy: In the event that a specific drug is not or is no longer on the formulary when the prescription is presented, the IPBMP shall provide notice of covered formulary alternatives to the prescriber promptly so that appropriate medication can be provided to the patient within 72 hours.
5. Drugs requiring prior authorization, shall be adjudicated by the IPBMP within 72 hours of receipt of the prescription.
6. Our AMA (a) promotes the value of online access to up-to-date and accurate prescription drug formulary plans from all insurance providers nationwide, and (b) supports state medical societies in advocating for state legislation to ensure online access to up-to-date and accurate prescription drug formularies for all insurance plans.

7. Our AMA will continue its efforts with the National Association of Insurance Commissioners addressing the development and management of pharmacy benefits.
8. Our AMA will develop model state legislation on the development and management of pharmacy benefits. (Sub. Res. 724, A-14; Appended: Res. 701, A-16; Appended: Alt. Res. 806, I-17; Reaffirmed: CMS Rep. 07, A-18; Reaffirmed: BOT Rep. 20, A-19; Reaffirmed: CMS Rep. 05, A-19; Reaffirmed: CMS Rep. 2, A-21)

Access to Health Plan Information Regarding Lower-Cost Prescription Options (H-120.919)

Our AMA will: (1) continue to support efforts to publish a Real-Time Prescription Benefit (RTPB) standard that meets the needs of all physicians and other prescribers, utilizing any electronic health record (EHR), and prescribing on behalf of any insured patient; (2) advocate that all payers (i.e., public and private prescription drug plans) be required to implement and keep up to date an RTPB standard tool that integrates with all EHR vendors, and that any changes that must be made to accomplish RTPB tool integration be accomplished with minimal disruption to EHR usability and cost to physicians and hospitals; and (3) develop and disseminate educational materials that will empower physicians to be prepared to optimally utilize RTPB tools and other health information technology tools that can be used to enhance communications between physicians and pharmacists to reduce the incidence of prescription abandonment. (CMS Rep. 2, I-21)

Pharmaceutical Costs (H-110.987)

1. Our AMA encourages Federal Trade Commission (FTC) actions to limit anticompetitive behavior by pharmaceutical companies attempting to reduce competition from generic manufacturers through manipulation of patent protections and abuse of regulatory exclusivity incentives.
2. Our AMA encourages Congress, the FTC and the Department of Health and Human Services to monitor and evaluate the utilization and impact of controlled distribution channels for prescription pharmaceuticals on patient access and market competition.
3. Our AMA will monitor the impact of mergers and acquisitions in the pharmaceutical industry.
4. Our AMA will continue to monitor and support an appropriate balance between incentives based on appropriate safeguards for innovation on the one hand and efforts to reduce regulatory and statutory barriers to competition as part of the patent system.
5. Our AMA encourages prescription drug price and cost transparency among pharmaceutical companies, pharmacy benefit managers and health insurance companies.
6. Our AMA supports legislation to require generic drug manufacturers to pay an additional rebate to state Medicaid programs if the price of a generic drug rises faster than inflation.
7. Our AMA supports legislation to shorten the exclusivity period for biologics.
8. Our AMA will convene a task force of appropriate AMA Councils, state medical societies and national medical specialty societies to develop principles to guide advocacy and grassroots efforts aimed at addressing pharmaceutical costs and improving patient access and adherence to medically necessary prescription drug regimens.
9. Our AMA will generate an advocacy campaign to engage physicians and patients in local and national advocacy initiatives that bring attention to the rising price of prescription drugs and help to put forward solutions to make prescription drugs more affordable for all patients.
10. Our AMA supports: (a) drug price transparency legislation that requires pharmaceutical manufacturers to provide public notice before increasing the price of any drug (generic, brand, or specialty) by ten percent or more each year or per course of treatment and provide justification for the price increase; (b) legislation that authorizes the Attorney General and/or the Federal Trade Commission to take legal action to address price gouging by pharmaceutical manufacturers and increase access to affordable drugs for patients; and (c) the expedited review of generic drug applications and prioritizing review of such applications when there is a drug

shortage, no available comparable generic drug, or a price increase of 10 percent or more each year or per course of treatment.

11. Our AMA advocates for policies that prohibit price gouging on prescription medications when there are no justifiable factors or data to support the price increase.
12. Our AMA will provide assistance upon request to state medical associations in support of state legislative and regulatory efforts addressing drug price and cost transparency.
13. Our AMA supports legislation to shorten the exclusivity period for FDA pharmaceutical products where manufacturers engage in anti-competitive behaviors or unwarranted price escalations.
14. Our AMA supports legislation that limits Medicare annual drug price increases to the rate of inflation. (CMS Rep. 2, I-15; Reaffirmed in lieu of: Res. 817, I-16; Appended: Res. 201, A-17; Reaffirmed in lieu of: Res. 207, A-17; Modified: Speakers Rep. 01, A-17; Appended: Alt. Res. 806, I-17; Reaffirmed: BOT Rep. 14, A-18; Appended: CMS Rep. 07, A-18; Appended: BOT Rep. 14, A-19; Reaffirmed: Res. 105, A-19; Appended: Res. 113, I-21; Reaffirmed in lieu of: Res. 810, I-22)

Price of Medicine (H-110.991)

Our AMA: (1) advocates that pharmacies be required to list the full retail price of the prescription on the receipt along with the co-pay that is required in order to better inform our patients of the price of their medications; (2) will pursue legislation requiring pharmacies, pharmacy benefit managers and health plans to inform patients of the actual cash price as well as the formulary price of any medication prior to the purchase of the medication; (3) opposes provisions in pharmacies' contracts with pharmacy benefit managers that prohibit pharmacists from disclosing that a patient's co-pay is higher than the drug's cash price; (4) will disseminate model state legislation to promote drug price and cost transparency and to prohibit "clawbacks"; (5) supports physician education regarding drug price and cost transparency, manufacturers' pricing practices, and challenges patients may encounter at the pharmacy point-of-sale; and (6) work with relevant organizations to advocate for increased transparency through access to meaningful and relevant information about medication price and out-of-pocket costs for prescription medications sold at both retail and mail order/online pharmacies, including but not limited to Medicare's drug-pricing dashboard. (CMS Rep. 6, A-03; Appended: Res. 107, A-07; Reaffirmed in lieu of: Res. 207, A-17; Appended: Alt. Res. 806, I-17; Reaffirmed: BOT Rep. 14, A-18; Appended: CMS Rep. 07, A-18; Reaffirmation: A-19; Appended: Res. 126, A-19)

Prescription Drug Price and Cost Transparency (D-110.988)

1. Our AMA will continue implementation of its TruthinRx grassroots campaign to expand drug pricing transparency among pharmaceutical manufacturers, pharmacy benefit managers and health plans, and to communicate the impact of each of these segments on drug prices and access to affordable treatment.
2. Our AMA will report back to the House of Delegates at the 2018 Interim Meeting on the progress and impact of the TruthinRx grassroots campaign. (Alt. Res. 806, I-17)

Abuse of Preauthorization Procedures (H-320.945)

Our AMA opposes the abuse of preauthorization by advocating the following positions:

- (1) Preauthorization should not be required where the medication or procedure prescribed is customary and properly indicated, or is a treatment for the clinical indication, as supported by peer-reviewed medical publications or for a patient currently managed with an established treatment regimen.
- (2) Third parties should be required to make preauthorization statistics available, including the percentages of approval or denial. These statistics should be provided by various categories,

e.g., specialty, medication or diagnostic test/procedure, indication offered, and reason for denial. (Sub. Res. 728, A-10; Reaffirmation I-10; Reaffirmation A-11; Reaffirmed: Res. 709, A-12; Reaffirmed: CMS Rep. 08, A-17; Reaffirmed: Res. 125, A-17; Reaffirmation: A-17 Reaffirmation: I-17; Reaffirmed: CMS Rep. 4, A-21; Reaffirmation: A-22)

Pharmacy Benefit Managers Impact on Patients (D-120.933)

Our AMA will: (1) gather more data on the erosion of physician-led medication therapy management in order to assess the impact pharmacy benefit manager (PBM) tactics may have on patient's timely access to medications, patient outcomes, and the physician-patient relationship; (2) examine issues with PBM-related clawbacks and direct and indirect remuneration (DIR) fees to better inform existing advocacy efforts; and (3) request from PBMs, and compile, data on the top twenty-five medication precertification requests and the percent of such requests approved after physician challenge. (Res. 225, A-18)