H-1472.2

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2021

SUBSTITUTE HOUSE BILL 1566

State of Washington 69th Legislature 2025 Regular Session

By House Health Care & Wellness (originally sponsored by Representatives Rule, Marshall, Shavers, Pollet, and Kloba)

READ FIRST TIME 02/21/25.

- AN ACT Relating to making improvements to transparency and accountability in the prior authorization determination process; amending RCW 48.43.830, 74.09.840, 41.05.845, 48.43.525, and 48.43.0161; and creating a new section.
- 5 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF WASHINGTON:
- 6 NEW SECTION. Sec. 1. (1) The legislature finds that health 7 insurance carriers, health plans, and managed care organizations are 8 the decision makers for the type and level of care covered for an 9 enrollee's health care benefits and are not responsible for determining or altering an enrollee's diagnosis or treatment plan. It 10 11 is not always transparent who the decision maker is or how decisions 12 are made in determining enrollee coverage for treatment, prescription 13 drugs, or services. Artificial intelligence is being increasingly 14 utilized by carriers, health plans, and managed care organizations to make or aid in decisions about medical necessity and coverage of 15 16 provider-recommended treatment.
 - (2) It is the intent of the legislature to increase transparency in the prior authorization process for health care coverage decisions and to ensure licensed physicians and licensed health professionals remain responsible for making determinations about coverage for treatment, prescription drugs, and services that are medically

p. 1 SHB 1566

- 1 necessary. If artificial intelligence tools are used to aid in the 2 decision-making process, standards must be put in place to ensure
- 3 these tools are not used to make inappropriate determinations that
- 4 could impact the health of an enrollee.

- **Sec. 2.** RCW 48.43.830 and 2023 c 382 s 1 are each amended to 6 read as follows:
 - (1) Each carrier offering a health plan issued or renewed on or after January 1, 2024, shall comply with the following standards related to prior authorization for health care services and prescription drugs:
 - (a) The carrier shall meet the following time frames for prior authorization determinations and notifications to a participating provider or facility that submits the prior authorization request through an electronic prior authorization process, as designated by each carrier:
 - (i) For electronic standard prior authorization requests, the carrier shall make a decision and notify the provider or facility of the results of the decision within three calendar days, excluding holidays, of submission of an electronic prior authorization request by the provider or facility that contains the necessary information to make a determination. If insufficient information has been provided to the carrier to make a decision, the carrier shall request any additional information from the provider or facility within one calendar day of submission of the electronic prior authorization request.
 - (ii) For electronic expedited prior authorization requests, the carrier shall make a decision and notify the provider or facility of the results of the decision within one calendar day of submission of an electronic prior authorization request by the provider or facility that contains the necessary information to make a determination. If insufficient information has been provided to the carrier to make a decision, the carrier shall request any additional information from the provider or facility within one calendar day of submission of the electronic prior authorization request.
 - (b) The carrier shall meet the following time frames for prior authorization determinations and notifications to a participating provider or facility that submits the prior authorization request through a process other than an electronic prior authorization process:

p. 2 SHB 1566

(i) For nonelectronic standard prior authorization requests, the carrier shall make a decision and notify the provider or facility of the results of the decision within five calendar days of submission of a nonelectronic prior authorization request by the provider or facility that contains the necessary information to make a determination. If insufficient information has been provided to the carrier to make a decision, the carrier shall request any additional information from the provider or facility within five calendar days of submission of the nonelectronic prior authorization request.

- (ii) For nonelectronic expedited prior authorization requests, the carrier shall make a decision and notify the provider or facility of the results of the decision within two calendar days of submission of a nonelectronic prior authorization request by the provider or facility that contains the necessary information to make a determination. If insufficient information has been provided to the carrier to make a decision, the carrier shall request any additional information from the provider or facility within one calendar day of submission of the nonelectronic prior authorization request.
- (c) In any instance in which a carrier has determined that a provider or facility has not provided sufficient information for making a determination under (a) and (b) of this subsection, a carrier may establish a specific reasonable time frame for submission of the additional information. This time frame must be communicated to the provider and enrollee with a carrier's request for additional information.
- (d) The carrier's prior authorization requirements must be described in detail and written in easily understandable language. The carrier shall make its most current prior authorization requirements and restrictions, including the written clinical review criteria, available to providers and facilities in an electronic format upon request. The prior authorization requirements must be based on peer-reviewed clinical review criteria. The clinical review criteria must be evidence-based criteria and must accommodate new and emerging information related to the appropriateness of clinical criteria with respect to black and indigenous people, other people of color, gender, and underserved populations. The clinical review criteria must be evaluated and updated, if necessary, at least annually.
- $((\frac{(2)}{2}))$ (e) When denying a prior authorization determination, the carrier shall include the credentials, board certifications, and

p. 3 SHB 1566

areas of specialty expertise and training of the provider who had clinical oversight over the determination in any notification sent to the health plan enrollee and provider requesting or referring the service.

- (2) (a) Carriers maintain the ability to make adjustments to policies and procedures that impact the applicability of their prior authorization requirements. Except as provided in (b) of this subsection, beginning August 1, 2025, these adjustments can only be made quarterly and go into effect either January 1st, April 1st, July 1st, or October 1st of any given calendar year. Notification of policy changes must be provided to all in-network providers at least 45 days prior to the quarterly update and must be available to providers in a single location on the carrier's website. The notification must be provided independent of other policy changes or provider notification publications and be easily accessible in electronic provider and enrollee portals.
- (b) Adjustments to policies and procedures that impact the applicability of prior authorization requirements to reflect federal food and drug administration approvals, national comprehensive cancer network guidelines, United States preventive services task force guidelines, or state or national public health emergencies may be made at any time and shall be posted on the website referenced in (a) of this subsection. Notification of adjustments made under this subsection must be provided to all in-network providers as soon as possible.
- (3) (a) Only a licensed physician or a licensed health professional working within their scope of practice may deny a prior authorization request based on medical necessity. The licensed physician or licensed health professional shall evaluate the specific clinical issues involved in the health care services requested by the requesting provider by reviewing and considering the requesting provider's recommendation, the enrollee's medical or other clinical history, as applicable, and individual clinical circumstances. An artificial intelligence tool shall not be the sole means used to deny, delay, or modify health care services. Algorithms may be used to process and approve prior authorization requests, but may not be used without human review to deny care based on a determination of medical necessity.
- (b) A carrier that uses an artificial intelligence tool for the purpose of prior authorization or prior authorization functions,

p. 4 SHB 1566

- 1 <u>based in whole or in part on medical necessity</u>, or that contracts
- 2 with or otherwise works through an entity that uses an artificial
- 3 <u>intelligence tool</u> for the purpose of prior authorization or prior
- 4 <u>authorization functions</u>, <u>based in whole or in part on medical</u>
- 5 <u>necessity</u>, shall ensure all of the following:

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- 6 <u>(i) The artificial intelligence tool bases its determination on</u>
 7 <u>the following information, as applicable:</u>
- 8 <u>(A) An enrollee's medical or other clinical history, including</u> 9 <u>demographic data; and</u>
- 10 (B) Individual clinical circumstances as presented by the 11 requesting provider;
- 12 <u>(ii) The artificial intelligence tool does not base its</u>
 13 <u>determination solely on a group data set;</u>
- 14 <u>(iii) The artificial intelligence tool's criteria and guidelines</u> 15 <u>comply with this chapter and applicable state and federal law;</u>
- 16 <u>(iv) The use of the artificial intelligence tool does not</u>
 17 <u>discriminate, directly or indirectly, against an enrollee in</u>
 18 violation of state or federal law;
- 19 <u>(v) The artificial intelligence tool is fairly and equitably</u>
 20 <u>applied, including in accordance with any applicable regulations and</u>
 21 <u>guidance issued by the federal department of health and human</u>
 22 services;
- 23 <u>(vi) The policies and procedures for using the artificial</u>
 24 <u>intelligence tool are open to audit by the office of the insurance</u>
 25 <u>commissioner under chapter 48.37 RCW;</u>
 - (vii) The artificial intelligence tool's performance, use, and outcomes are periodically reviewed by the carrier to maximize accuracy and reliability; and
 - (viii) Patient data is not used beyond its intended and stated purpose, consistent with chapter 70.02 RCW and the federal health insurance portability and accountability act of 1996, 42 U.S.C. Sec. 1320d et al., as applicable.
 - (4) (a) Each carrier shall build and maintain a prior authorization application programming interface that automates the process for in-network providers to determine whether a prior authorization is required for health care services, identify prior authorization information and documentation requirements, and facilitate the exchange of prior authorization requests and determinations from its electronic health records or practice management system. The application programming interface must support

p. 5 SHB 1566

the exchange of prior authorization requests and determinations for health care services beginning January 1, 2025, and must:

- (i) Use health level 7 fast health care interoperability resources in accordance with standards and provisions defined in 45 C.F.R. Sec. 170.215 and 45 C.F.R. Sec. 156.22(3)(b);
- (ii) Automate the process to determine whether a prior authorization is required for durable medical equipment or a health care service;
- 9 (iii) Allow providers to query the carrier's prior authorization 10 documentation requirements;
 - (iv) Support an automated approach using nonproprietary open workflows to compile and exchange the necessary data elements to populate the prior authorization requirements that are compliant with the federal health insurance portability and accountability act of 1996 or have an exception from the federal centers for medicare and medicaid services; ((and))
 - (v) Indicate that a prior authorization denial or authorization of a service less intensive than that included in the original request is an adverse benefit determination and is subject to the carrier's grievance and appeal process under RCW 48.43.535; and
 - (vi) Include the credentials, board certifications, and areas of specialty expertise and training of the provider who had clinical oversight over the determination in any notification sent to the health plan enrollee and provider requesting or referring the service.
 - (b) Each carrier shall establish and maintain an interoperable electronic process or application programming interface that automates the process for in-network providers to determine whether a prior authorization is required for a covered prescription drug. The application programming interface must support the exchange of prior authorization requests and determinations for prescription drugs, including information on covered alternative prescription drugs, beginning January 1, 2027, and must:
 - (i) Allow providers to identify prior authorization information and documentation requirements;
 - (ii) Facilitate the exchange of prior authorization requests and determinations from its electronic health records or practice management system, and may include the necessary data elements to populate the prior authorization requirements that are compliant with the federal health insurance portability and accountability act of

p. 6 SHB 1566

1 1996 or have an exception from the federal centers for medicare and 2 medicaid services; and

- (iii) Indicate that a prior authorization denial or authorization of a drug other than the one included in the original prior authorization request is an adverse benefit determination and is subject to the carrier's grievance and appeal process under RCW 48.43.535.
- (c) If federal rules related to standards for using an application programming interface to communicate prior authorization status to providers are not finalized by the federal centers for medicare and medicaid services by September 13, 2023, the requirements of (a) of this subsection may not be enforced until January 1, 2026.
- (d)(i) If a carrier determines that it will not be able to satisfy the requirements of (a) of this subsection by January 1, 2025, the carrier shall submit a narrative justification to the commissioner on or before September 1, 2024, describing:
- (A) The reasons that the carrier cannot reasonably satisfy the requirements;
 - (B) The impact of noncompliance upon providers and enrollees;
- 21 (C) The current or proposed means of providing health information 22 to the providers; and
- 23 (D) A timeline and implementation plan to achieve compliance with the requirements.
 - (ii) The commissioner may grant a one-year delay in enforcement of the requirements of (a) of this subsection $((\frac{2}{2}))$ if the commissioner determines that the carrier has made a good faith effort to comply with the requirements.
 - (iii) This subsection $((\frac{(2)}{(2)}))$ $\underline{(4)}$ (d) shall not apply if the delay in enforcement in (c) of this subsection takes effect because the federal centers for medicare and medicaid services did not finalize the applicable regulations by September 13, 2023.
 - (e) By September 13, 2023, and at least every six months thereafter until September 13, 2026, the commissioner shall provide an update to the health care policy committees of the legislature on the development of rules and implementation guidance from the federal centers for medicare and medicaid services regarding the standards for development of application programming interfaces and interoperable electronic processes related to prior authorization functions. The updates should include recommendations, as

p. 7 SHB 1566

- 1 appropriate, on whether the status of the federal rule development aligns with the provisions of chapter 382, Laws of 2023. 2 commissioner also shall report on any actions by the federal centers 3 for medicare and medicaid services to exercise enforcement discretion 4 related to the implementation and maintenance of an application 5 6 programming interface for prior authorization functions. commissioner shall consult with the health care authority, carriers, 7 providers, and consumers on the development of these updates and any 8 9 recommendations.
- 10 $((\frac{3}{3}))$ Nothing in this section applies to prior 11 authorization determinations made pursuant to RCW 48.43.761.
- 12 (((4))) (6) This section applies to prior authorization functions 13 carried out by health care benefit managers, as defined in RCW 14 48.200.020, under direct or indirect contract with a carrier.
- 15 <u>(7) The commissioner may adopt any rules necessary to implement</u> 16 this section.
 - (8) For the purposes of this section:
 - (a) "Artificial intelligence" means the use of machine learning and related technologies that use data to train statistical models for the purpose of enabling computer systems to perform tasks normally associated with human intelligence or perception, such as computer vision, speech or natural language processing, and content generation. "Artificial intelligence" includes generative artificial intelligence.
 - (b) "Expedited prior authorization request" means a request by a provider or facility for approval of a health care service or prescription drug where:
 - (i) The passage of time:

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- 29 (A) Could seriously jeopardize the life or health of the 30 enrollee;
- 31 (B) Could seriously jeopardize the enrollee's ability to regain 32 maximum function; or
 - (C) In the opinion of a provider or facility with knowledge of the enrollee's medical condition, would subject the enrollee to severe pain that cannot be adequately managed without the health care service or prescription drug that is the subject of the request; or
- 37 (ii) The enrollee is undergoing a current course of treatment 38 using a nonformulary drug.

p. 8 SHB 1566

1 ((\(\frac{(b)}{(b)}\)) (c) "Generative artificial intelligence" means an
2 artificial intelligence system that generates novel data or content
3 based on a foundation model.

- (d) "Machine learning" means the process by which artificial intelligence is developed using data and algorithms to draw inferences therefrom to automatically adapt or improve its accuracy without explicit programming.
- (e) "Standard prior authorization request" means a request by a provider or facility for approval of a health care service or prescription drug where the request is made in advance of the enrollee obtaining a health care service or prescription drug that is not required to be expedited.
- **Sec. 3.** RCW 74.09.840 and 2023 c 382 s 3 are each amended to 14 read as follows:
 - (1) Beginning January 1, 2024, the authority shall require each managed care organization to comply with the following standards related to prior authorization for health care services and prescription drugs:
 - (a) The managed care organization shall meet the following time frames for prior authorization determinations and notifications to a participating provider or facility that submits the prior authorization request through an electronic prior authorization process, as designated by each managed care organization:
 - (i) For electronic standard prior authorization requests, the managed care organization shall make a decision and notify the provider or facility of the results of the decision within three calendar days, excluding holidays, of submission of an electronic prior authorization request by the provider or facility that contains the necessary information to make a determination. If insufficient information has been provided to the managed care organization to make a decision, the managed care organization shall request any additional information from the provider or facility within one calendar day of submission of the electronic prior authorization request.
 - (ii) For electronic expedited prior authorization requests, the managed care organization shall make a decision and notify the provider or facility of the results of the decision within one calendar day of submission of an electronic prior authorization request by the provider or facility that contains the necessary

p. 9 SHB 1566

information to make a determination. If insufficient information has been provided to the managed care organization to make a decision, the managed care organization shall request any additional information from the provider or facility within one calendar day of submission of the electronic prior authorization request.

- (b) The managed care organization shall meet the following time frames for prior authorization determinations and notifications to a participating provider or facility that submits the prior authorization request through a process other than an electronic prior authorization process described in subsection $((\frac{1}{2}))$ of this section:
- (i) For nonelectronic standard prior authorization requests, the managed care organization shall make a decision and notify the provider or facility of the results of the decision within five calendar days of submission of a nonelectronic prior authorization request by the provider or facility that contains the necessary information to make a determination. If insufficient information has been provided to the managed care organization to make a decision, the managed care organization shall request any additional information from the provider or facility within five calendar days of submission of the nonelectronic prior authorization request.
- (ii) For nonelectronic expedited prior authorization requests, the managed care organization shall make a decision and notify the provider or facility of the results of the decision within two calendar days of submission of a nonelectronic prior authorization request by the provider or facility that contains the necessary information to make a determination. If insufficient information has been provided to the managed care organization to make a decision, the managed care organization shall request any additional information from the provider or facility within one calendar day of submission of the nonelectronic prior authorization request.
- (c) In any instance in which a managed care organization has determined that a provider or facility has not provided sufficient information for making a determination under (a) and (b) of this subsection, a managed care organization may establish a specific reasonable time frame for submission of the additional information. This time frame must be communicated to the provider and enrollee with a managed care organization's request for additional information.

p. 10 SHB 1566

(d) The prior authorization requirements of the managed care organization must be described in detail and written in easily understandable language. The managed care organization shall make its most current prior authorization requirements and restrictions, including the written clinical review criteria, available to providers and facilities in an electronic format upon request. The prior authorization requirements must be based on peer-reviewed clinical review criteria. The clinical review criteria must be evidence-based criteria and must accommodate new and emerging information related to the appropriateness of clinical criteria with respect to black and indigenous people, other people of color, gender, and underserved populations. The clinical review criteria must be evaluated and updated, if necessary, at least annually.

- (((2))) (e) When denying a prior authorization determination, the managed care organization shall include the credentials, board certifications, and areas of specialty expertise and training of the provider who had clinical oversight over the determination in any notification sent to the managed care enrollee and provider requesting or referring the service.
- (2) (a) Managed care organizations maintain the ability to make adjustments to policies and procedures that impact the applicability of their prior authorization requirements. Except as provided in (b) of this subsection, beginning August 1, 2025, these adjustments can only be made quarterly and go into effect either January 1st, April 1st, July 1st, or October 1st of any given calendar year. Notification of policy changes must be provided to all in-network providers at least 45 days prior to the quarterly update and must be available to providers in a single location on the managed care organization's website. The notification must be provided independent of other policy changes or provider notification publications and be easily accessible in electronic provider and enrollee portals.
- (b) Adjustments to policies and procedures that impact the applicability of prior authorization requirements to reflect federal food and drug administration approvals, national comprehensive cancer network guidelines, United States preventive services task force guidelines, or state or national public health emergencies may be made at any time and shall be posted on the website referenced in (a) of this subsection. Notification of adjustments made under this subsection must be provided to all in-network providers as soon as possible.

p. 11 SHB 1566

(3) (a) Only a licensed physician or a licensed health professional working within their scope of practice may deny a prior authorization request based on medical necessity. The licensed physician or licensed health professional shall evaluate the specific clinical issues involved in the health care services requested by the requesting provider by reviewing and considering the requesting provider's recommendation, the enrollee's medical or other clinical history, as applicable, and individual clinical circumstances. An artificial intelligence tool shall not be the sole means used to deny, delay, or modify health care services. Algorithms may be used to process and approve prior authorization requests, but may not be used without human review to deny care based on a determination of medical necessity.

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- (b) A managed care organization that uses an artificial intelligence tool for the purpose of prior authorization or prior authorization functions, based in whole or in part on medical necessity, or that contracts with or otherwise works through an entity that uses an artificial intelligence tool for the purpose of prior authorization or prior authorization functions, based in whole or in part on medical necessity, shall ensure all of the following:
- 21 <u>(i) The artificial intelligence tool bases its determination on</u> 22 <u>the following information</u>, as applicable:
- 23 <u>(A) An enrollee's medical or other clinical history, including</u>
 24 <u>demographic data; and</u>
- 25 <u>(B) Individual clinical circumstances as presented by the</u> 26 <u>requesting provider;</u>
- 27 <u>(ii) The artificial intelligence tool does not base its</u> 28 <u>determination solely on a group data set;</u>
- 29 <u>(iii) The artificial intelligence tool's criteria and guidelines</u> 30 <u>comply with this chapter and applicable state and federal law;</u>
- 31 <u>(iv) The use of the artificial intelligence tool does not</u>
 32 <u>discriminate, directly or indirectly, against an enrollee in</u>
 33 violation of state or federal law;
- 34 <u>(v) The artificial intelligence tool is fairly and equitably</u>
 35 <u>applied, including in accordance with any applicable regulations and</u>
 36 <u>guidance issued by the federal department of health and human</u>
 37 services;
- (vi) The policies and procedures for using the artificial intelligence tool are open to audit by the authority consistent with RCW 74.09.200;

p. 12 SHB 1566

(vii) The artificial intelligence tool's performance, use, and outcomes are periodically reviewed by the managed care organization to maximize accuracy and reliability; and

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- (viii) Patient data is not used beyond its intended and stated purpose, consistent with chapter 70.02 RCW and the federal health insurance portability and accountability act of 1996, 42 U.S.C. Sec. 1320d et al., as applicable.
- (4) By July 1, 2027, the authority shall publish a list of 8 treatments, prescription drugs, equipment, and services, along with 9 their applicable billing codes, that specifies under which 10 circumstances prior authorization is required, prohibited, or has 11 12 other uniform application across the medical assistance program under this chapter. The authority must consider applicable state and 13 federal laws when deciding which services are not subject to prior 14 authorization. The authority shall focus on existing prior 15 authorization requirements and treatments, prescription drugs, 16 17 equipment, and services that are treated inconsistently in the medical assistance program. The authority shall update the list at 18 least annually and provide notice and an opportunity for public 19 comment prior to finalizing the list. Nothing in this subsection 20 alters existing obligations of the authority and managed care 21 organizations to ensure enrollee access to treatments, prescription 22 23 drugs, equipment, and services that are not included in the list. Nothing in this section prohibits the authority and managed care 24 25 organizations from applying other utilization management strategies, consistent with state and federal law, for services for which prior 26 27 authorization is not required.
 - (5)(a) Each managed care organization shall build and maintain a prior authorization application programming interface that automates the process for in-network providers to determine whether a prior authorization is required for health care services, identify prior authorization information and documentation requirements, and facilitate the exchange of prior authorization requests and determinations from its electronic health records or practice management system. The application programming interface must support the exchange of prior authorization requests and determinations for health care services beginning January 1, 2025, and must:
- (i) Use health level 7 fast health care interoperability resources in accordance with standards and provisions defined in 45 C.F.R. Sec. 170.215 and 45 C.F.R. Sec. 156.22(3)(b);

p. 13 SHB 1566

1 (ii) Automate the process to determine whether a prior 2 authorization is required for durable medical equipment or a health 3 care service;

- (iii) Allow providers to query the managed care organization's prior authorization documentation requirements;
- (iv) Support an automated approach using nonproprietary open workflows to compile and exchange the necessary data elements to populate the prior authorization requirements that are compliant with the federal health insurance portability and accountability act of 1996 or have an exception from the federal centers for medicare and medicaid services; and
- (v) Indicate that a prior authorization denial or authorization of a service less intensive than that included in the original request is an adverse benefit determination and is subject to the managed care organization's grievance and appeal process under RCW 48.43.535.
- (b) Each managed care organization shall establish and maintain an interoperable electronic process or application programming interface that automates the process for in-network providers to determine whether a prior authorization is required for a covered prescription drug. The application programming interface must support the exchange of prior authorization requests and determinations for prescription drugs, including information on covered alternative prescription drugs, beginning January 1, 2027, and must:
- (i) Allow providers to identify prior authorization information and documentation requirements;
- (ii) Facilitate the exchange of prior authorization requests and determinations from its electronic health records or practice management system, and may include the necessary data elements to populate the prior authorization requirements that are compliant with the federal health insurance portability and accountability act of 1996 or have an exception from the federal centers for medicare and medicaid services; ((and))
- (iii) Indicate that a prior authorization denial or authorization of a drug other than the one included in the original prior authorization request is an adverse benefit determination and is subject to the managed care organization's grievance and appeal process under RCW 48.43.535; and
- (iv) Include the credentials, board certifications, and areas of specialty expertise and training of the provider who had clinical

p. 14 SHB 1566

- oversight over the determination in any notification sent to the managed care enrollee and provider requesting or referring the service.
- 4 (c) If federal rules related to standards for using an application programming interface to communicate prior authorization status to providers are not finalized by September 13, 2023, the requirements of (a) of this subsection may not be enforced until January 1, 2026.
- 9 (d)(i) If a managed care organization determines that it will not 10 be able to satisfy the requirements of (a) of this subsection by 11 January 1, 2025, the managed care organization shall submit a 12 narrative justification to the authority on or before September 1, 13 2024, describing:
- 14 (A) The reasons that the managed care organization cannot reasonably satisfy the requirements;

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- (B) The impact of noncompliance upon providers and enrollees;
- 17 (C) The current or proposed means of providing health information 18 to the providers; and
- 19 (D) A timeline and implementation plan to achieve compliance with 20 the requirements.
 - (ii) The authority may grant a one-year delay in enforcement of the requirements of (a) of this subsection $((\frac{2}{2}))$ if the authority determines that the managed care organization has made a good faith effort to comply with the requirements.
 - (iii) This subsection $((\frac{(2)}{(2)}))$ (5) (d) shall not apply if the delay in enforcement in (c) of this subsection takes effect because the federal centers for medicare and medicaid services did not finalize the applicable regulations by September 13, 2023.
- (((3))) (6) This section applies to prior authorization functions carried out by health care benefit managers, as defined in RCW 48.200.020, under direct or indirect contract with a carrier.
- 32 (7) The authority may adopt any rules necessary to implement this section.
- 34 <u>(8)</u> Nothing in this section applies to prior authorization determinations made pursuant to RCW 71.24.618 or 74.09.490.
 - $((\frac{4}{1}))$ (9) For the purposes of this section:
- 37 (a) "Artificial intelligence" means the use of machine learning
 38 and related technologies that use data to train statistical models
 39 for the purpose of enabling computer systems to perform tasks
 40 normally associated with human intelligence or perception, such as

p. 15 SHB 1566

- computer vision, speech or natural language processing, and content generation. "Artificial intelligence" includes generative artificial intelligence.
- 4 <u>(b)</u> "Expedited prior authorization request" means a request by a 5 provider or facility for approval of a health care service or 6 prescription drug where:
 - (i) The passage of time:

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- 8 (A) Could seriously jeopardize the life or health of the 9 enrollee;
- 10 (B) Could seriously jeopardize the enrollee's ability to regain 11 maximum function; or
 - (C) In the opinion of a provider or facility with knowledge of the enrollee's medical condition, would subject the enrollee to severe pain that cannot be adequately managed without the health care service or prescription drug that is the subject of the request; or
- 16 (ii) The enrollee is undergoing a current course of treatment 17 using a nonformulary drug.
 - (((b))) <u>(c) "Generative artificial intelligence" means an artificial intelligence system that generates novel data or content based on a foundation model.</u>
- 21 (d) "Machine learning" means the process by which artificial 22 intelligence is developed using data and algorithms to draw 23 inferences therefrom to automatically adapt or improve its accuracy 24 without explicit programming.
- 25 <u>(e)</u> "Standard prior authorization request" means a request by a 26 provider or facility for approval of a health care service or 27 prescription drug where the request is made in advance of the 28 enrollee obtaining a health care service or prescription drug that is 29 not required to be expedited.
- 30 **Sec. 4.** RCW 41.05.845 and 2023 c 382 s 2 are each amended to 31 read as follows:
- 32 (1) A health plan offered to public employees, retirees, and 33 their covered dependents under this chapter issued or renewed on or 34 after January 1, 2024, shall comply with the following standards 35 related to prior authorization for health care services and 36 prescription drugs:
- 37 (a) The health plan shall meet the following time frames for 38 prior authorization determinations and notifications to a 39 participating provider or facility that submits the prior

p. 16 SHB 1566

1 authorization request through an electronic prior authorization 2 process:

- (i) For electronic standard prior authorization requests, the health plan shall make a decision and notify the provider or facility of the results of the decision within three calendar days, excluding holidays, of submission of an electronic prior authorization request by the provider or facility that contains the necessary information to make a determination. If insufficient information has been provided to the health plan to make a decision, the health plan shall request any additional information from the provider or facility within one calendar day of submission of the electronic prior authorization request.
- (ii) For electronic expedited prior authorization requests, the health plan shall make a decision and notify the provider or facility of the results of the decision within one calendar day of submission of an electronic prior authorization request by the provider or facility that contains the necessary information to make a determination. If insufficient information has been provided to the health plan to make a decision, the health plan shall request any additional information from the provider or facility within one calendar day of submission of the electronic prior authorization request.
- (b) The health plan shall meet the following time frames for prior authorization determinations and notifications to a participating provider or facility that submits the prior authorization request through a process other than an electronic prior authorization process described in subsection ((-(2+))) (4) of this section:
- (i) For nonelectronic standard prior authorization requests, the health plan shall make a decision and notify the provider or facility of the results of the decision within five calendar days of submission of a nonelectronic prior authorization request by the provider or facility that contains the necessary information to make a determination. If insufficient information has been provided to the health plan to make a decision, the health plan shall request any additional information from the provider or facility within five calendar days of submission of the nonelectronic prior authorization request.
- (ii) For nonelectronic expedited prior authorization requests, the health plan shall make a decision and notify the provider or

p. 17 SHB 1566

facility of the results of the decision within two calendar days of submission of a nonelectronic prior authorization request by the provider or facility that contains the necessary information to make a determination. If insufficient information has been provided to the health plan to make a decision, the health plan shall request any additional information from the provider or facility within one calendar day of submission of the nonelectronic prior authorization request.

- (c) In any instance in which the health plan has determined that a provider or facility has not provided sufficient information for making a determination under (a) and (b) of this subsection, the health plan may establish a specific reasonable time frame for submission of the additional information. This time frame must be communicated to the provider and enrollee with the health plan's request for additional information.
- (d) The prior authorization requirements of the health plan must be described in detail and written in easily understandable language. The health plan shall make its most current prior authorization requirements and restrictions, including the written clinical review criteria, available to providers and facilities in an electronic format upon request. The prior authorization requirements must be based on peer-reviewed clinical review criteria. The clinical review criteria must be evidence-based criteria and must accommodate new and emerging information related to the appropriateness of clinical criteria with respect to black and indigenous people, other people of color, gender, and underserved populations. The clinical review criteria must be evaluated and updated, if necessary, at least annually.
- (((2))) (e) When denying a prior authorization determination, the health plan shall include the credentials, board certifications, and areas of specialty expertise and training of the provider who had clinical oversight over the determination in any notification sent to the health plan enrollee and provider requesting or referring the service.
- (2) (a) Health plans maintain the ability to make adjustments to policies and procedures that impact the applicability of their prior authorization requirements. Except as provided in (b) of this subsection, beginning August 1, 2025, these adjustments can only be made quarterly and go into effect either January 1st, April 1st, July 1st, or October 1st of any given calendar year. Notification of

p. 18 SHB 1566

policy changes must be provided to all in-network providers at least
45 days prior to the quarterly update and must be available to
providers in a single location on the health plan's website. The
notification must be provided independent of other policy changes or
provider notification publications and be easily accessible in
electronic provider and enrollee portals.

- (b) Adjustments to policies and procedures that impact the applicability of prior authorization requirements to reflect federal food and drug administration approvals, national comprehensive cancer network quidelines, United States preventive services task force quidelines, or state or national public health emergencies may be made at any time and shall be posted on the website referenced in (a) of this subsection. Notification of adjustments made under this subsection must be provided to all in-network providers as soon as possible.
- (3) (a) Only a licensed physician or a licensed health professional working within their scope of practice may deny a prior authorization request based on medical necessity. The licensed physician or licensed health professional shall evaluate the specific clinical issues involved in the health care services requested by the requesting provider by reviewing and considering the requesting provider's recommendation, the enrollee's medical or other clinical history, as applicable, and individual clinical circumstances. An artificial intelligence tool shall not be the sole means used to deny, delay, or modify health care services. Algorithms may be used to process and approve prior authorization requests, but may not be used without human review to deny care based on a determination of medical necessity.
- (b) A health plan that uses an artificial intelligence tool for the purpose of prior authorization or prior authorization functions, based in whole or in part on medical necessity, or that contracts with or otherwise works through an entity that uses an artificial intelligence tool for the purpose of prior authorization or prior authorization functions, based in whole or in part on medical necessity, shall ensure all of the following:
- 36 <u>(i) The artificial intelligence tool bases its determination on the following information, as applicable:</u>
- 38 <u>(A) An enrollee's medical or other clinical history, including</u>
 39 demographic data; and

p. 19 SHB 1566

1 (B) Individual clinical circumstances as presented by the 2 requesting provider;

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- (ii) The artificial intelligence tool does not base its determination solely on a group data set;
- (iii) The artificial intelligence tool's criteria and guidelines 5 6 comply with this chapter and applicable state and federal law;
- (iv) The use of the artificial intelligence tool does not 7 discriminate, directly or indirectly, against an enrollee in 8 violation of state or federal law;
- (v) The artificial intelligence tool is fairly and equitably 10 applied, including in accordance with any applicable regulations and 11 quidance <u>issued</u> by the <u>federal department of health and human</u> 12 13 services;
- (vi) The policies and procedures for using the artificial 14 intelligence tool is open to audit by the office of the insurance 15 16 commissioner;
 - (vii) The artificial intelligence tool's performance, use, and outcomes are periodically reviewed by the health plan to maximize accuracy and reliability; and
 - (viii) Patient data is not used beyond its intended and stated purpose, consistent with chapter 70.02 RCW and the federal health insurance portability and accountability act of 1996, U.S.C. Sec. 1320d et al., as applicable.
 - (4) (a) Each health plan offered to public employees, retirees, and their covered dependents under this chapter shall build and maintain a prior authorization application programming interface that automates the process for in-network providers to determine whether a prior authorization is required for health care services, identify prior authorization information and documentation requirements, and facilitate the exchange of prior authorization requests and determinations from its electronic health records or practice management system. The application programming interface must support the exchange of prior authorization requests and determinations for health care services beginning January 1, 2025, and must:
 - (i) Use health level 7 fast health care interoperability resources in accordance with standards and provisions defined in 45 C.F.R. Sec. 170.215 and 45 C.F.R. Sec. 156.22(3)(b);
- (ii) Automate the process to determine whether a prior 38 39 authorization is required for durable medical equipment or a health 40 care service;

p. 20 SHB 1566 1 (iii) Allow providers to query the health plan's prior authorization documentation requirements;

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- (iv) Support an automated approach using nonproprietary open workflows to compile and exchange the necessary data elements to populate the prior authorization requirements that are compliant with the federal health insurance portability and accountability act of 1996 or have an exception from the federal centers for medicare and medicaid services; ((and))
- (v) Indicate that a prior authorization denial or authorization of a service less intensive than that included in the original request is an adverse benefit determination and is subject to the health plan's grievance and appeal process under RCW 48.43.535; and
- (vi) Include the credentials, board certifications, and areas of specialty expertise and training of the provider who had clinical oversight over the determination in any notification sent to the health plan enrollee and provider requesting or referring the service.
- (b) Each health plan offered to public employees, retirees, and their covered dependents under this chapter shall establish and maintain an interoperable electronic process or application programming interface that automates the process for in-network providers to determine whether a prior authorization is required for a covered prescription drug. The application programming interface must support the exchange of prior authorization requests and determinations for prescription drugs, including information on covered alternative prescription drugs, beginning January 1, 2027, and must:
- (i) Allow providers to identify prior authorization information and documentation requirements;
- (ii) Facilitate the exchange of prior authorization requests and determinations from its electronic health records or practice management system, and may include the necessary data elements to populate the prior authorization requirements that are compliant with the federal health insurance portability and accountability act of 1996 or have an exception from the federal centers for medicare and medicaid services; and
- (iii) Indicate that a prior authorization denial or authorization of a drug other than the one included in the original prior authorization request is an adverse benefit determination and is

p. 21 SHB 1566 subject to the health plan's grievance and appeal process under RCW 48.43.535.

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- (c) If federal rules related to standards for using an application programming interface to communicate prior authorization status to providers are not finalized by the federal centers for medicare and medicaid services by September 13, 2023, the requirements of (a) of this subsection may not be enforced until January 1, 2026.
- 9 (d)(i) If the health plan determines that it will not be able to 10 satisfy the requirements of (a) of this subsection by January 1, 11 2025, the health plan shall submit a narrative justification to the 12 authority on or before September 1, 2024, describing:
- 13 (A) The reasons that the health plan cannot reasonably satisfy the requirements;
 - (B) The impact of noncompliance upon providers and enrollees;
- 16 (C) The current or proposed means of providing health information 17 to the providers; and
 - (D) A timeline and implementation plan to achieve compliance with the requirements.
 - (ii) The authority may grant a one-year delay in enforcement of the requirements of (a) of this subsection $((\frac{2}{2}))$ if the authority determines that the health plan has made a good faith effort to comply with the requirements.
 - (iii) This subsection $((\frac{(2)}{(2)}))$ $\underline{(4)}$ (d) shall not apply if the delay in enforcement in (c) of this subsection takes effect because the federal centers for medicare and medicaid services did not finalize the applicable regulations by September 13, 2023.
- 28 $((\frac{3}{3}))$ Nothing in this section applies to prior 29 authorization determinations made pursuant to RCW 41.05.526.
- 30 (((4))) (6) This section applies to prior authorization functions 31 carried out by health care benefit managers, as defined in RCW 32 48.200.020, under direct or indirect contract with a carrier.
- 33 (7) The commissioner may adopt any rules necessary to implement 34 this section.
 - (8) For the purposes of this section:
- 36 (a) "Artificial intelligence" means the use of machine learning
 37 and related technologies that use data to train statistical models
 38 for the purpose of enabling computer systems to perform tasks
 39 normally associated with human intelligence or perception, such as
 40 computer vision, speech or natural language processing, and content

p. 22 SHB 1566

- 1 generation. "Artificial intelligence" includes generative artificial
 2 intelligence.
 - (b) "Expedited prior authorization request" means a request by a provider or facility for approval of a health care service or prescription drug where:
 - (i) The passage of time:

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- 7 (A) Could seriously jeopardize the life or health of the 8 enrollee;
- 9 (B) Could seriously jeopardize the enrollee's ability to regain 10 maximum function; or
 - (C) In the opinion of a provider or facility with knowledge of the enrollee's medical condition, would subject the enrollee to severe pain that cannot be adequately managed without the health care service or prescription drug that is the subject of the request; or
- 15 (ii) The enrollee is undergoing a current course of treatment 16 using a nonformulary drug.
- 17 (((b))) <u>(c) "Generative artificial intelligence" means an</u>
 18 <u>artificial intelligence system that generates novel data or content</u>
 19 <u>based on a foundation model.</u>
- 20 (d) "Machine learning" means the process by which artificial
 21 intelligence is developed using data and algorithms to draw
 22 inferences therefrom to automatically adapt or improve its accuracy
 23 without explicit programming.
 - (e) "Standard prior authorization request" means a request by a provider or facility for approval of a health care service or prescription drug where the request is made in advance of the enrollee obtaining a health care service that is not required to be expedited.
- $((\frac{(5)}{(5)}))$ (9) This section shall not apply to coverage provided under the medicare part C or part D programs set forth in Title XVIII of the social security act of 1965, as amended.
- 32 **Sec. 5.** RCW 48.43.525 and 2000 c 5 s 9 are each amended to read 33 as follows:
- 34 (1) A health carrier that offers a health plan shall not 35 retrospectively deny coverage or retrospectively modify to a service 36 less intensive than that included in the original request for 37 emergency and nonemergency care that had prior authorization, 38 including for medical necessity, under the plan's written policies at 39 the time the care was rendered, unless:

p. 23 SHB 1566

1 <u>(a) The prior authorization was based upon a material</u>
2 misrepresentation by the provider, facility, or covered person; or

- (b) The underlying health plan coverage is lawfully rescinded, canceled, or terminated retrospectively through the date of service.
- (2) Retrospective denials of services with prior authorization or retrospective modification to less intensive services due to a change in the carrier's determination of medical necessity are prohibited, shall not be considered adverse benefit determinations, and will not be required to follow the standard appeals processes in RCW 48.43.530 or any carrier policies related to their own grievance and appeals process. If an enrollee or the provider requesting the original authorization demonstrates the authorization was valid per the plan's written policies, then the carrier will deem the authorization approved and payable. Interest will be assessed on the associated claim submitted by the provider at the rate of one percent per month, retroactive to the original date of the authorization request.
- 17 (3) The commissioner shall adopt, in rule, standards for this 18 section after considering relevant standards adopted by national 19 managed care accreditation organizations and state agencies that 20 purchase managed health care services.
- **Sec. 6.** RCW 48.43.0161 and 2023 c 382 s 4 are each amended to 22 read as follows:
 - (1) By ((October 1, 2020,)) January 1, 2026, and annually thereafter, for individual and group health plans issued by a carrier that has written at least one percent of the total accident and health insurance premiums written by all companies authorized to offer accident and health insurance in Washington in the most recently available year, the carrier shall report to the commissioner the following aggregated and deidentified data related to the carrier's prior authorization practices and experience for the prior plan year:
 - (a) The total number of prior authorization requests, approvals, and denials. The carrier must report these totals separately for approvals or denials made by the carrier directly and for approvals or denials made by a health care benefit manager as defined in RCW 48.200.020 that is delegated to make prior authorization determinations, either directly or indirectly, on behalf of the carrier. In the report, carriers must also indicate:

p. 24 SHB 1566

- 1 <u>(i) The percentage of total denials that were aided by artificial</u>
 2 <u>intelligence tools; and</u>
 - (ii) The percent of prior authorization determinations made after the standard and expedited authorization request turnaround times stated in RCW 48.43.830;
 - (b) Lists of the 10 inpatient medical or surgical codes:

- (i) With the highest total number of prior authorization requests during the previous plan year, including the total number of prior authorization requests for each code and the percent of approved requests for each code;
- (ii) With the highest percentage of approved prior authorization requests during the previous plan year, including the total number of prior authorization requests for each code and the percent of approved requests for each code; and
- (iii) With the highest percentage of prior authorization requests that were initially denied and then subsequently approved on appeal, including the total number of prior authorization requests for each code and the percent of requests that were initially denied and then subsequently approved for each code;
 - (((b))) <u>(c)</u> Lists of the 10 outpatient medical or surgical codes:
- (i) With the highest total number of prior authorization requests during the previous plan year, including the total number of prior authorization requests for each code and the percent of approved requests for each code;
- (ii) With the highest percentage of approved prior authorization requests during the previous plan year, including the total number of prior authorization requests for each code and the percent of approved requests for each code; and
- (iii) With the highest percentage of prior authorization requests that were initially denied and then subsequently approved on appeal, including the total number of prior authorization requests for each code and the percent of requests that were initially denied and then subsequently approved for each code;
- ((-(c))) <u>(d)</u> Lists of the 10 inpatient mental health and substance use disorder service codes:
- (i) With the highest total number of prior authorization requests during the previous plan year, including the total number of prior authorization requests for each code and the percent of approved requests for each code;

p. 25 SHB 1566

(ii) With the highest percentage of approved prior authorization requests during the previous plan year, including the total number of prior authorization requests for each code and the percent of approved requests for each code; and

- (iii) With the highest percentage of prior authorization requests that were initially denied and then subsequently approved on appeal, including the total number of prior authorization requests for each code and the percent of requests that were initially denied and then subsequently approved for each code;
- (((d))) <u>(e)</u> Lists of the 10 outpatient mental health and substance use disorder service codes:
- (i) With the highest total number of prior authorization requests during the previous plan year, including the total number of prior authorization requests for each code and the percent of approved requests for each code;
- (ii) With the highest percentage of approved prior authorization requests during the previous plan year, including the total number of prior authorization requests for each code and the percent of approved requests for each code; and
- (iii) With the highest percentage of prior authorization requests that were initially denied and then subsequently approved on appeal, including the total number of prior authorization requests for each code and the percent of requests that were initially denied and then subsequently approved;
 - $((\frac{(e)}{(e)}))$ (f) Lists of the 10 durable medical equipment codes:
- (i) With the highest total number of prior authorization requests during the previous plan year, including the total number of prior authorization requests for each code and the percent of approved requests for each code;
- (ii) With the highest percentage of approved prior authorization requests during the previous plan year, including the total number of prior authorization requests for each code and the percent of approved requests for each code; and
- (iii) With the highest percentage of prior authorization requests that were initially denied and then subsequently approved on appeal, including the total number of prior authorization requests for each code and the percent of requests that were initially denied and then subsequently approved for each code;
- $((\frac{f}{f}))$ <u>(g)</u> Lists of the 10 diabetes supplies and equipment 40 codes:

p. 26 SHB 1566

- (i) With the highest total number of prior authorization requests during the previous plan year, including the total number of prior authorization requests for each code and the percent of approved requests for each code;
- (ii) With the highest percentage of approved prior authorization requests during the previous plan year, including the total number of prior authorization requests for each code and the percent of approved requests for each code; and
- (iii) With the highest percentage of prior authorization requests that were initially denied and then subsequently approved on appeal, including the total number of prior authorization requests for each code and the percent of requests that were initially denied and then subsequently approved for each code;
 - $((\frac{g}{g}))$ (h) Lists of the 10 prescription drugs:
- (i) With the highest total number of prior authorization requests during the previous plan year, including the total number of prior authorization requests for each prescription drug and the percent of approved requests for each prescription drug;
- (ii) With the highest percentage of approved prior authorization requests during the previous plan year, including the total number of prior authorization requests for each prescription drug and the percent of approved requests for each prescription drug; and
- (iii) With the highest percentage of prior authorization requests that were initially denied and then subsequently approved on appeal, including the total number of prior authorization requests for each prescription drug and the percent of requests that were initially denied and then subsequently approved for each prescription drug; and
- $((\frac{h}{)})$ (i) The average determination response time in hours for prior authorization requests to the carrier in total reported under (a) of this subsection and with respect to each code reported under $((\frac{h}{)})$ (b) through $((\frac{h}{)})$ (h) of this subsection for each of the following categories of prior authorization:
 - (i) Expedited decisions;

- (ii) Standard decisions; and
- (iii) Extenuating circumstances decisions.
- (2) (a) By January 1, 2021, and annually thereafter, the commissioner shall aggregate and deidentify the data collected under subsection (1) of this section into a standard report and may not identify the name of the carrier that submitted the data. The commissioner must make the report available to interested parties.

p. 27 SHB 1566

1 (b) The report must contain trend data for total authorization 2 requests, approvals, and denials by plan and health care benefit 3 managers.

- (3) The commissioner may request additional information from carriers reporting data under this section.
- (4) The commissioner may adopt rules to implement this section. In adopting rules, the commissioner must consult stakeholders including carriers, health care practitioners, health care facilities, and patients.
- (5) For the purpose of this section, "prior authorization" means a mandatory process that a carrier or its designated or contracted representative requires a provider or facility to follow before a service is delivered, to determine if a service is a benefit and meets the requirements for medical necessity, clinical appropriateness, level of care, or effectiveness in relation to the applicable plan, including any term used by a carrier or its designated or contracted representative to describe this process.

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p. 28 SHB 1566