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February 7, 2022

Nyasha Smith, Secretary
Council of the District of Columbia
1350 Pennsylvania Avenue, N.W.
Washington, DC 20004

Dear Secretary Smith,

Today, I, along with Councilmembers Gray, Allen, Lewis George, and Bonds, am introducing the "Prior Authorization Reform Amendment Act of 2022." Please find enclosed a signed copy of the legislation.

In recent years, health insurers across the United States have adopted a new practice, wherein patients and their medical providers are required to seek prior authorization for certain medications, medical procedures, or other medical care. Prior authorization requirements mean that an insurer is able to overrule the treatment prescribed by a patient's medical provider—and make that determination without ever seeing the patient or their medical records. While insurers may claim that prior authorization is currently required for only complex procedures, a growing number of basic, everyday treatments require prior authorization; in fact, more and more, it seems that the cost of treatment, not a determination of medical necessity for different care, is driving what medications and procedures require prior authorization.

When unregulated, prior authorization requirements can and do cause meaningful harm to patients. Seeking a prior authorization (or appealing a denial) can take weeks or even months, during which time patients will typically go without care. This not only means the patient continues to suffer, but some conditions may worsen over time. Unfortunately, these lengthy delays inure to the benefit of insurers as patients, not wanting to wait for care, may seek different, possibly less effective treatment that doesn't require prior authorization. And, where that alternate treatment is less expensive, the insurer saves money.

Making matters worse, insurers may not make prior authorization requirements clear and accessible to patients. Some insurers may not include full information on prior authorization requirements on their website, and decline to provide clarity via e-mail or the phone; often, patients may learn the grounds for a

denial of a prior authorization and how to cure via letters sent snail mail, further delaying care for these patients. These delays and the lack of clarity on how one might successfully receive prior authorization for a treatment also push patients to seek cheaper, sometimes less effective care that does not require this approval. It is clear: unregulated prior authorization requirements result in slower, worse quality care for patients, with the only benefits flowing to insurance companies.

In fact, prior authorization requirements also create problems for medical providers. Doctors report investing a growing number of staff hours to processing prior authorization requests or appeals on behalf of patients; that time is even greater in states, like the District, that do not regulate these processes, as insurers may use different forms, processes, and review standards. Some medical providers have even reported having to bring on additional staff to handle prior authorizations. This means higher overhead for doctor's offices—costs that ultimately get passed on to patients. Dealing with these processes also mean medical providers have less time to care for patients.

More than forty states have passed legislation or adopted regulations to address insurer prior authorization practices, and this legislation would bring the District in line with those jurisdictions. The bill sets explicit, reasonable timelines for insurers to respond to prior authorization requests and appeals, and lays out the qualifications of personnel qualified to make these determinations (as some insurers have personnel without appropriate subject matter training reviewing prior authorization requests). The legislation would also clarify how insurers are to make information on prior authorization determinations available to patients and their medical providers, and require that insurers accept and use the electronic NCPDP SCRIPT Standard ePA transaction, the recommended, standardized method for submission and review of prior authorization requests. Finally, and perhaps most importantly, the bill would prohibit insurers from requiring prior authorization for a treatment based solely on cost. Separately, this legislation would make a small change to require that employers provide timely notice to employees of medications and treatments covered under their insurer's standard health benefit plan, but not covered under the negotiated terms of the employer's bespoke plan; this language will help ensure employees have full knowledge of what is and what isn't covered under various employer health benefit plans, and can make a fully educated choice about which coverage to choose.

This legislation is being introduced with the input and support of the Medical Society of the District of Columbia. As noted, more than forty states have already acted to regulate this practice, recognizing the meaningful impact needless delays and denials of care due to prior authorization practices have on patients' health and wellbeing; of note, those states have not seen meaningful changes in the cost of medications or care due to regulation this practice. Importantly, with this

legislation, the District will help ensure patients do not face unnecessarily barriers to timely, medically appropriate care.

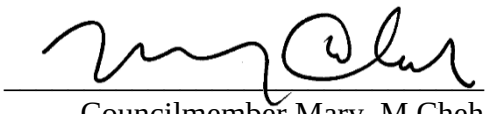
Should you have any questions about this legislation, please contact my Legislative Director, Michael Porcello, at mporcello@dccouncil.us or (202) 724-8062.

Thank you.

Best,

Mary M. Cheh

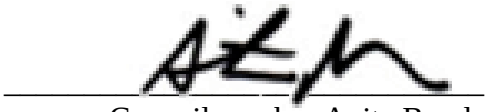
Councilmember Vincent C. Gray



Councilmember Mary. M Cheh

Councilmember Janeese Lewis George

Councilmember Charles Allen



Councilmember Anita Bonds

A BILL

IN THE COUNCIL OF THE DISTRICT OF COLUMBIA

To prescribe the manner in which a utilization review entity is to make available information on prior authorization requirements and restrictions; to set notice requirements for prior authorization determinations; to lay out the minimum length that a prior authorization is to be considered valid, to set the qualifications for personnel authorized to make adverse determinations; to permit enrollees to appeal an adverse determination and to set deadlines for submissions of appeals; to set qualifications for personnel authorized to review appeals of adverse determinations; to prescribe utilization review entities' obligations in terms of reviewing requests for prior authorization for non-urgent, urgent, and emergency; to permit utilization review entities to require prior authorization only based on a determination of medical necessity for different care and to prohibit a utilization review entity from requiring prior authorization for a treatment solely based on cost; to prohibit a utilization review entity from revoking, limiting, condition, or restricting a prior authorization if care was provided within 45 days of receipt of the prior authorization; to require that a utilization review entity honor a prior authorization granted by a previous utilization review entity for at least the first 60 days of coverage; to clarify that health services are to be deemed authorized if a utilization review entity fails to comply with this act; and to require utilization review entities using prior authorization to make certain statistics available to the public; to amend the Uniform Health Insurance Claims Forms Act of 1995 to require that, by January 1, 2023, all utilization review

entities accept and respond to prior authorization requests using the NCPDP SCRIPT Standard ePA transaction; and to amend the Health Insurance Portability and Accountability Federal Law Conformity and No-Fault Motor Vehicle Insurance Act of 1998 to require that employers provide notice of employees of treatments, including particular services or medications, not included in a negotiated health benefit plan but including in the standard health benefit plan or formulary offered by the health insurer.

BE IT ENACTED BY THE COUNCIL OF THE DISTRICT OF COLUMBIA, That this act may be cited as the "Prior Authorization Reform Amendment Act of 2022".

Sec. 2. Definitions.

(a) "Adverse determination" means a decision by a utilization review entity that the health care services furnished or proposed to be furnished to an enrollee are not medically necessary or are experimental or investigational; and benefit coverage is therefore denied, reduced, or terminated.

(b) "Emergency health care services" means those health care services that are provided in an emergency facility after the sudden onset of a medical condition that manifests itself by symptoms of sufficient severity, including severe pain, that the absence of immediate medical attention could reasonably be expected by a prudent layperson, who possesses an average knowledge of health and medicine, to result in placing the patient's health in serious jeopardy, serious impairment to bodily function, or serious dysfunction of any bodily organ or part.

(c) "Enrollee" means an individual eligible to receive health care benefits by a health insurer pursuant to a health plan or other health insurance coverage. The term "enrollee" includes an enrollee's legally authorized representative.

(d) "Medication assisted treatment" means the use of medications, commonly in combination with counseling and behavioral therapies, to provide a comprehensive approach to the treatment of substance use disorders.

(e) “Prior authorization” means the process by which utilization review entities determine the medical necessity or medical appropriateness of covered health care services prior to the rendering of such health care services. “Prior authorization” also includes any health insurer or utilization review entity’s requirement that an enrollee or health care provider notify the health insurer or utilization review entity prior to providing a health care service.

(f) “Urgent health care service” means:

(1) A health care service that, in the opinion of a physician with knowledge of the enrollee’s medical condition, if not receiving an expedited prior authorization:

(A) Could seriously jeopardize the life or health of the enrollee or the ability of the enrollee to regain maximum function; or

(B) Could subject the enrollee to severe pain that cannot be adequately managed without the care or treatment that is the subject of the utilization review; or

(2) Medication assisted treatment.

(g) “Utilization review entity” means an individual or entity that performs prior authorization for one or more of the following entities:

(i) An employer with employees in the District;

(ii) An insurer that writes health insurance policies;

(iii) A preferred provider organization, or health maintenance organization; and

(iv) Any other individual or entity that provides, offers to provide, or administers hospital, outpatient, medical, prescription drug, or other health benefits to a person treated by a health care provider in the District under a policy, plan, or contract.

Sec. 3. Prior Authorization Requirements and Restrictions.

(a)(1) A utilization review entity shall make available any current prior authorization requirements and restrictions, including formulary, ("prior authorization requirements") in at least the following ways:

(A) Posting of the prior authorization requirements on its website, in a manner accessible to enrollees, health care providers, and the general public and without an account;

(B) Emailing or providing a hard copy of the prior authorization requirements to enrollees and health care providers upon request by telephone or in writing, including a request via email; and

(C) Providing information on prior authorization requirements, upon request, to enrollees or health care providers over the telephone.

(b) Prior authorization requirements shall:

(1) Be described in detail and easily understandable language;

(2) Include any written clinical criteria;

(3) Include a comprehensive listing of all drugs that require a prior authorization; and

(4) Include the process for submitting and standards for considering, including evidence-based guidelines, where possible, requests for:

(i) A prior authorization;

(ii) A reauthorization of a prior authorization after a previous prior authorization has expired, and

(iii) Appeals of an adverse determination.

(c)(1) If a utilization review entity intends either to amend or replace the prior authorization requirements, the changes shall not be deemed effective until the utilization review entity's website has been updated to reflect the new language.

Sec. 4. Prior Authorization Determinations.

(a)(1) Where a utilization review entity makes a determination to grant or deny a prior authorization, the enrollee and the health care provider submitting the request for a prior authorization must be provided with notice within 24 hours of the determination.

(2) Notice provided under this section must include:

(A) The name and qualifications, pursuant to Section 6 of this Act, of the personnel making the determination; and

(B) For an adverse determination:

(i) The grounds under the prior authorization requirements for denying the prior authorization; and

(ii) Information on the enrollee's right to appeal, the process to file an appeal, and a listing of information necessary to support an appeal of the adverse determination.

(c)(1) A utilization review entity shall make information available on its website to enrollees and the enrollee's health care provider on active requests for prior authorization and requests made, at a minimum, to that utilization review entity in the preceding five years, and shall include:

(A) A copy of any information or materials submitted by the enrollee's health care provider to request or support a request for a prior authorization or reauthorization, or appeal an adverse determination; the information or materials shall clearly show the date of any

submissions by the health care provider, the health care service prescribed by the health care provider, and the basis, if any, provided by the health care provider for the health care service; and

(B) A copy of notices of determination provided to the enrollee and health care provider pursuant to subsection (a) of this section;

(b) Upon request of the enrollee or health care provider, a utilization review entity shall make information on an adverse determination available via telephone, including the basis under the prior authorization requirements for denying the prior authorization, information on the enrollee's right to appeal, the process to file an appeal, and any information necessary to support a successful appeal.

Sec. 5. Length of prior authorization.

(a) Except for as provided in subsection (b) of this section, a prior authorization for shall be valid for at least one year from the date the health care provider receives the prior authorization. The prior authorization shall remain valid regardless of any changes in dosage for a prescription drug prescribed by the health care provider; provided, that utilization review entities may rescind prior authorization for dosages exceeding limitations set in federal or District law or regulations.

(b) If a utilization review entity requires a prior authorization for a health care service for the treatment of a chronic or long-term care condition, the prior authorization shall remain valid for the length of the treatment and the utilization review entity may not require the enrollee to re-obtain a prior authorization for the health care service.

Sec. 6. Personnel qualified to make adverse determinations.

(c) A utilization review entity must ensure that all adverse determinations are made by a physician who:

(1) Possesses a current and valid non-restricted license to practice medicine in the District of Columbia;

(2) Is of the same specialty as a physician who typically manages the medical condition or disease or provides the health care service involved in the request;

(3) Makes the adverse determination under the clinical direction of one of the utilization review entity's medical directors who is responsible for the provision of health care services provided to enrollees in the District of Columbia, and who is licensed in the District of Columbia.

Sec. 7. Consultation prior to issuing an adverse determination

(a) If a utilization review entity is questioning the medical necessity of a health care service, the utilization review entity must notify the enrollee's health care provider that medical necessity is being questioned. Prior to issuing an adverse determination, the enrollee's health care provider must have the opportunity to discuss the medical necessity of the health care service on the telephone with the physician who will be responsible for determining authorization of the health care service under review.

Sec. 8. Appeals.

(a)(1) A utilization review entity shall allow an enrollee to appeal an adverse determination. Any appeal submitted within 15 calendar days of the enrollee's receipt of notice of the adverse determination shall be treated as timely.

(2) A utilization review entity shall permit an appeal to be submitted at least via its website or in hard copy.

(3) Appeals submitted in hard copy shall be considered timely where the appeal is postmarked within 15 calendar days of the enrollee's receipt of notice of the adverse determination.

(b)(1) The enrollee and the health care provider submitting the original request for a prior authorization must be provided notice within 24 hours of a determination on an appeal of an adverse determination.

(2) Notice provided under this subsection must include:

(A) The name and qualifications, pursuant to Section 9 of this Act, of the physician reviewing the appeal; and

(B) The grounds under the prior authorization requirements for the physician's determination.

Sec. 9. Personnel qualified to review appeals.

(a) A utilization entity must ensure that all appeals are reviewed by a physician. The physician must:

(1) Possess a current and valid non-restricted license to practice medicine in the District;

(2) Be in active practice in the same specialty as a physician who typically manages the medical condition or disease and have practiced that specialty for at least 5 years;

(3) Be knowledgeable of, and have experience providing, the health care services under appeal;

(4) Not be employed by a utilization review entity or be under contract with the utilization review entity other than to participate in one or more of the utilization review entity's

health care provider networks or to perform reviews of appeals, or otherwise have any financial interest in the outcome of the appeal;

(5) Not have been directly involved in making the adverse determination; and

(b) In reviewing an appeal, the physician must consider all known clinical aspects of the health care service under review, including but not limited to, a review of all pertinent medical records provided to the utilization review entity by the enrollee's health care provider, any relevant records provided to the utilization review entity by a health care facility, and any medical literature provided to the utilization review entity by the health care provider.

Sec. 10. Utilization review entities' obligations with respect to prior authorizations in non-urgent, urgent, and emergency circumstances.

(a) If a utilization review entity requires prior authorization of a health care service, the utilization review entity must grant the prior authorization or make an adverse determination and notify the enrollee and the enrollee's health care provider of the prior authorization or adverse determination within 3 business days of obtaining all information required; if the determination is not made within that time frame, such services shall be deemed approved.

(b) A utilization review entity must grant a prior authorization or make an adverse determination concerning urgent care services and notify the enrollee and the enrollee's health care provider of that determination, not later than 24 hours after receiving all information required if the determination is not made within that time frame, such services shall be deemed approved.

(c)(1) A utilization review entity cannot require prior authorization for pre-hospital transportation or for the provision of emergency health care services, including emergency health care services to screen and stabilize an enrollee.

(2) A utilization review entity shall allow an enrollee and the enrollee's health care provider a minimum of 24 hours following an emergency admission or provision of emergency health care services for the enrollee or health care provider to notify the utilization review entity of the admission or provision of health care services. If the admission or health care service occurs on a holiday or weekend, a utilization review entity cannot require notification until the next business day after the admission or provision of the health care services.

(3) If a health care provider certifies in writing to a utilization review entity within 72 hours of an enrollee's admission that the enrollee's condition required emergency health care services, that certification will create a presumption that the emergency health care services were medically necessary and such presumption may be rebutted only if the utilization review entity can establish, with clear and convincing evidence, that the emergency health care services were not medically necessary.

(4) The medical necessity or appropriateness of emergency health care services cannot be based on whether those services were provided by participating or nonparticipating providers. Restrictions on coverage of emergency health care services provided by nonparticipating providers cannot be greater than restrictions that apply when those services are provided by participating providers.

(d) For purposes of this section, "required information" includes the results of any face-to-face clinical evaluation or second opinion that may be required.

Sec. 11. Prior Authorization Limitations.

(a) A utilization review entity may only require prior authorization for a health care service based on a determination of medical necessity for different care or that the proposed care

is experimental or investigational in nature. A utilization review entity may not require prior authorization solely based on the cost of a health care service.

(b) A utilization review entity may not require prior authorization for the provision of medication-assisted treatment for the treatment of opioid-use disorder.

Sec. 12. Retrospective denial.

The utilization review entity may not revoke, limit, condition, or restrict a prior authorization if care is provided within 45 working days from the date the health care provider received the prior authorization.

Sec. 13. Continuity of care for enrollees.

(a) A utilization review entity shall honor a prior authorization granted to an enrollee from a previous utilization review entity for at least the initial 60 days of an enrollee's coverage under a new health plan; provided, that the utilization review entity may condition honoring the prior authorization on receipt of information documenting the previous utilization review entity's grant of prior authorization.

(b) During the time period described in paragraph (a) of this subsection, a utilization review entity may perform its own review to grant a prior authorization.

(c) If there is a change in coverage of, or approval criteria for, a previously authorized health care service, the change in coverage or approval criteria shall not apply to an enrollee who received prior authorization before the effective date of the change for the length of the prior authorization's eligibility.

(d) A utilization review entity shall continue to honor a prior authorization it has granted to an enrollee when the enrollee changes products under the same health insurance company.

Sec. 14. Health care services deemed authorized if a utilization review entity fails to comply with the requirements of this Act.

Any failure by a utilization review entity to comply with the deadlines and other requirements specified in this Act shall result in the health care services in question to be deemed authorized by the utilization review entity.

Sec. 15. Data Collection.

Utilization review entities using prior authorization shall make statistics available regarding prior authorizations, adverse determinations, and appeals on their website in a readily accessible format. They should include categories for approvals, adverse determinations, and appeals broken down by:

(1) Specialty of physician reviewing the request for prior authorization or appeal;

(2) Type of medication, test, procedure, or treatment ("health care service");

(3) Indication offered;

(4) Reason for denial;

(5) If appealed;

(6) If approved or denied on appeal;

(7) The time between submission of the request for prior authorization and the utilization review entity's determination; and

(8) The time between submission of an appeal of an adverse determination and the utilization review entity's determination.

Sec. 16. The Uniform Health Insurance Claim Forms Act of 1995, effective February 27, 1996 (D.C. Law 11-89; D.C. Code §31-3201) is amended by adding a new subsection (c) to read as follows:

"(c)(1) No later than January 1, 2023, a utilization review entity must accept and respond to prior authorization requests under the pharmacy benefit through a secure electronic transmission using the NCPDP SCRIPT Standard ePA transactions. Facsimile, propriety payer portals, electronic forms, or any other technology not directly integrated with a physician's electronic health record/electronic prescribing system shall not be considered secure electronic transmission.

"(2) For the purposes of this subsection:

"(A) "NCPDP SCRIPT Standard" means the National Council for Prescription Drug Programs SCRIPT Standard Version 2013101, or the most recent standard adopted by the United States Department of Health and Human Services.

"(B) "Prior authorization" means the process by which utilization review entities determine the medical necessity or medical appropriateness of covered health care services prior to the rendering of such health care services. "Prior authorization" also includes any health insurer or utilization review entity's requirement that an enrollee or health care provider notify the health insurer or utilization review entity prior to providing a health care service.

"(C) "Utilization review entity" means an individual or entity that performs prior authorization for one or more of the following entities:

"(i) An employer with employees in the District;

"(ii) An insurer that writes health insurance policies;

"(iii) a preferred provider organization, or health maintenance organization; and

"(iv) any other individual or entity that provides, offers to provide, or administers hospital, outpatient, medical, prescription drug, or other health benefits to a person treated by a health care provider in the District under a policy, plan, or contract."

Sec. 17. The Health Insurance Portability and Accountability Federal Law Conformity and No-Fault Motor Vehicle Insurance Act of 1998, effective April 13, 1999 (D.C. Law 12-209; D.C. Official Code § 31-3301.01), is amended by adding a new Section 313e to read as follows:

"Section 313e. Negotiated health benefit plans.

"(a) Where an employer negotiates an employee health benefit plan with a health insurer such that treatment, including particular services or medications, covered under the negotiated health benefit plan offered to employees differs from the standard health benefit plan or formulary offered by the health insurer, the employer shall provide notice to all employees, regardless of whether they are enrolled in the negotiated health benefit plan, of any treatments, including particular services or medications, covered under the standard health benefit plan or formulary but not covered under the negotiated health benefit plan or formulary offered to employees.

"(b) Notice under subsection (a) of this section shall be provided to employees:

"(1) At least 30 days prior to the conclusion of any open enrollment period; and

"(2) Within 30 days after the employer and health insurer finalize terms of coverage under a negotiated health benefit plan.

"(c) For the purposes of

Sec. 18. Fiscal impact statement.

The Council adopts the fiscal impact statement in the committee report as the fiscal impact statement required by section 4a of the General Legislative Procedures Act of 1975, approved October 16, 2006 (120 Stat. 2038; D.C. Official Code § 1-301.47a).

Sec. 19. Effective date.

This act shall take effect following approval by the Mayor (or in the event of veto by the Mayor, action by the Council to override the veto), a 30-day period of congressional review as provided in section 602(c)(1) of the District of Columbia Home Rule Act, approved December 24, 1973 (87 Stat. 813; D.C. Official Code § 1-206.02(c)(1)), and publication in the District of Columbia Register.