



**MEMORANDUM**

November 22, 2021

**To:** Senator Roger Marshall  
Attention: Charlotte Pineda

**From:**



**Subject:** Summary of S. 3018, the “Improving Seniors’ Timely Access to Care Act of 2021”

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This memorandum responds to your request for a summary of S. 3018, the “Improving Seniors’ Timely Access to Care Act of 2021” as introduced on October 20, 2021, by Senator Marshall, and referred to the Committee on Finance on that date.<sup>1</sup> You also requested background information and current law relevant to S. 3018.<sup>2</sup>

Because these issues are of general interest to Congress, information contained in this memorandum may be used to respond to other congressional requests. However, information regarding your request will remain confidential.

The memorandum includes the following:

- A brief overview of S. 3018,
- Background information on the Medicare program related to the modifications and additions made by S. 3018, including descriptions of coverage and payment,
- A discussion of prior authorization (PA) and its use in Medicare, in particular in Medicare Advantage (MA) and Part D (Prescription Drug Program), and
- A detailed summary of the bill.

## Brief Overview of S. 3018

S. 3018 would amend Title XVIII of the Social Security Act (SSA) to require Medicare Advantage (MA) plans to establish electronic PA processes that adhere to specified requirements, including “real-time” decisions for an identified subset of PA requests. Generally, PA is a process through which a physician or other health care provider must obtain advance approval from the insurer, including a MA plan when appropriate, in order that payment would be made for a service or item furnished to an enrollee.

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<sup>1</sup> See bill at Congress.gov, <https://www.congress.gov/bill/117th-congress/senate-bill/3018/text>.

<sup>2</sup> This memorandum is an update of a memorandum provided to your office on November 7, 2019 on H.R. 3107, the “Improving Seniors’ Timely Access to Care Act in 2019.”

Under the bill, MA plans would be required to submit certain information about PAs to the Secretary of Health and Human Services (HHS Secretary), including data on denials, overturned decisions, and the average and median amount of time it took a plan to make a determination. Plans would be required to make specified information available to prospective and contracted providers and suppliers, and beneficiaries. The HHS Secretary would be required to promulgate regulations that: (1) provide guidance to MA plans regarding establishment of PA decision-making criteria and beneficiary access to that criteria and (2) specify requirements for the development, use, and update of PA policies to ensure transparency, inclusiveness, and beneficiary continuity of care.

## Background

Medicare is a federal program that pays for covered health care services of qualified beneficiaries.<sup>3</sup> Medicare consists of four distinct parts:

- Part A (Hospital Insurance, or HI) covers inpatient hospital services, skilled nursing care, hospice care, and some home health services.
- Part B (Supplementary Medical Insurance, or SMI) covers physician services, outpatient services, durable medical equipment, and some home health and preventive services.
- Part C (Medicare Advantage, or MA) is a private plan option for beneficiaries that covers all required Parts A and B services, except hospice and organ acquisition for kidney transplants.<sup>4</sup> MA plans may also offer additional benefits not covered under Parts A and B.
- Part D is a voluntary program that covers outpatient prescription drug benefits, either as a stand-alone prescription drug plan (PDP), or integrated with Part C benefits as an MA-PD.

## Coverage

In general, for Medicare to pay for an item or service, the item or service must meet several criteria: it must be eligible for one of the defined Medicare benefit categories (e.g., hospital care, physician's services); it must not be an item that is specifically, statutorily excluded from coverage (e.g., hearing aids); and it must be "reasonable and necessary for the diagnosis or treatment of illness or injury, or to improve the functioning of a malformed body member."<sup>5</sup> Alternatively, an item or service may be specified in statute as being covered by Medicare even if it would not otherwise meet the above criteria (e.g., preventive services).

Exactly which specific items and services are considered "reasonable and necessary" and covered by the Medicare program can be determined nationally or locally. A national coverage determination (NCD) is a policy developed by the HHS Secretary that a particular item or service is reasonable and necessary, and therefore covered by Medicare nationally. In the absence of an NCD, Medicare administrative contractors (MACs) may issue local coverage determinations (LCD) that establish whether a particular service is reasonable and necessary, and therefore covered by Medicare within the MAC's service area. Among other elements, NCDs and LCDs can include an explanation of the clinical circumstances under which an

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<sup>3</sup> CRS Report R40425, *Medicare Primer*.

<sup>4</sup> SSA Section 1852(a)(1)(B). If an MA enrollee chooses to participate in hospice, or is eligible for an organ transplant, these options are paid for through original Medicare.

<sup>5</sup> SSA Section 1862(a)(1)(A).

item or service is considered reasonable and necessary, and what evidence is necessary to support a coverage request.<sup>6</sup>

In general, the coverage determinations that apply to original fee-for-service (FFS) Medicare (Parts A and B) also apply to MA plans. However, there are situations where MA plans are allowed to standardize benefits or delay implementation. For example, if an MA plan service area spans more than one MAC region and therefore is subject to more than one coverage determination, the MA plan can choose to standardize its coverage policy based on the coverage determination that is most beneficial to the enrollee.<sup>7</sup> In addition, if there is an NCD or legislative change that results in an expansion of coverage with a substantial cost to an MA plan, and the change was not taken into account during the yearly bidding process to determine MA plan payment (described below), the change would not apply to the MA plan until the first contract year after the change could be taken into account.<sup>8</sup>

Under Medicare Part D, in order for an outpatient prescription drug to be paid, it must meet the definition of a covered drug and it must also be included on the formulary of the Part D plan. Part D drugs are defined as: (1) outpatient prescription drugs approved by the Food and Drug Administration (FDA) and used for a medically accepted indication; (2) biological products that may be dispensed only upon a prescription and that are licensed under the Public Health Service Act (PHSA) and produced at a licensed establishment; (3) insulin (including medical supplies associated with the injection of insulin); and (4) vaccines licensed under the PHSA. Drugs can also be treated as part of a plan's formulary as the result of a beneficiary coverage determination or appeal.<sup>9</sup>

Certain drugs are excluded from Part D coverage by law, including drugs specifically excluded from coverage under the state-federal Medicaid program. The exclusion applies to: (1) drugs used for anorexia, weight loss, or weight gain; (2) fertility drugs; (3) drugs used for cosmetic purposes or hair growth; (4) drugs for symptomatic relief for coughs and colds; (5) prescription vitamins and minerals; and (6) covered drugs when the manufacturer requires, as a condition of sale, that associated tests be purchased exclusively from the manufacturer. Drugs used for the treatment of sexual or erectile dysfunction are excluded from coverage unless they are used to treat another condition for which the drug has been approved by the FDA.

There is no central formulary, or list of covered drugs, in the Medicare Part D program. However, Part D plans must cover at least two drugs in each class and category and substantially all drugs in six protected classes that include: immunosuppressants, antidepressants, antipsychotics, anticonvulsants, antiretrovirals, and antineoplastic (cancer) classes.<sup>10</sup>

## Payment

Payment under the Medicare program for covered benefits follows statutory requirements, as implemented through rules. Some benefits, such as physician services and some durable medical equipment, are paid through fee schedules, which are lists of Medicare payments for specific items and services that are calculated according to statutorily specified formulas and take into account the labor and capital resources required to provide the item or service. In such cases, the total payment depends on the

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<sup>6</sup> The Medicare Coverage Database on the CMS website allows one to find NCDs, LCDs, or both, by geographic area, or by searching for key terms, or codes. Coverage policies in some cases can be very detailed and assume a greater-than-lay-person's understanding of medicine or technology making them challenging to read by individuals without medical training. [<https://www.cms.gov/medicare-coverage-database/>]

<sup>7</sup> SSA Section 1852(a)(2)(C).

<sup>8</sup> SSA Section 1852(a)(5).

<sup>9</sup> See covered drug and Part D drug at 42 C.F.R. Section 423.100.

<sup>10</sup> CRS Report R40611, *Medicare Part D Prescription Drug Benefit*.

number and volume of items and services furnished and billed. Other services, such as inpatient hospital care and home health care, are paid under prospective payment systems, where payment amounts are predetermined for a defined period and/or diagnosis, and are based on an episode of care rather than a measure of the resources used in treating the patient. Other payments, such as those for MA plans and Part D plans, are based on bids and/or benchmarks, which are then used to determine per person monthly payments to the plans for providing covered benefits. The payment mechanisms for MA and Part D are explained in more detail below.

## Medicare Advantage Payments

As discussed above, MA plans are paid a per-person monthly (capitated) amount by Medicare. The HHS Secretary determines a plan's payment by comparing its bid to a benchmark. A *bid* is the plan's estimated cost of providing Medicare-covered services (excluding hospice, and specified organ acquisition, but including the cost of medical services, administration, and profit). A *benchmark* is the maximum amount the federal government will pay for providing those services in the plan's service area, and is based on a percentage of per capita spending in original (FFS) Medicare. If a plan's bid is less than the benchmark, the plan's payment equals its bid plus a rebate. The rebate must be returned to enrollees in the form of additional benefits, reduced cost sharing, reduced Medicare Part B or Part D premiums, or some combination of these options. If a plan's bid is equal to or above the benchmark, its payment equals the benchmark amount; each enrollee in that plan will pay an additional premium that is equal to the amount by which the bid exceeds the benchmark. Additionally, payments to plans are risk adjusted to take into account the demographic and health history of those who actually enroll in the plan.<sup>11</sup>

Plan payments are determined yearly as part of contracting process between the HHS Secretary and the private insurers that wish to offer an MA benefit. The HHS Secretary is required to publish information related to benchmarks by not later than the first Monday in April in the year prior to the calendar year covered by the contract.<sup>12</sup> Historically, the HHS Secretary would concurrently publish a Final Call Letter including final policies and bidding instructions. However, the HHS Secretary has codified many of the policies once addressed in the yearly Final Call Letter, and going forward will publish yearly Bidding Instructions.<sup>13</sup> Private insurers submit their bids along with other required application material at the beginning of each June. Contracts are signed by the end of August, in time for open enrollment in the fall before the contract year.<sup>14</sup>

## Part D Payments

Similar to payments for MA plans, Medicare makes risk-adjusted payments to Part D prescription drug plan sponsors (insurers) on a monthly per-capita basis based on the cost estimates in the sponsors' annual plan bids. Bids are based on a plan's estimated cost for providing "standard coverage" to an enrollee in average health. The Part D standard benefit is defined in statute, and updated annually to account for Part D drug price inflation. In practice, although plan bids are based on "standard coverage," most plan sponsors choose to offer alternative coverage (such as coverage with tiered formulary cost sharing for prescription drugs), which must be at least actuarially equivalent to standard coverage or enhanced coverage, which has a higher actuarial value. Unlike MA plans, payments to Part D plans include not only

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<sup>11</sup> See also, CRS Report R45494, *Medicare Advantage (MA)–Proposed Benchmark Update and Other Adjustments for CY2020: In Brief*.

<sup>12</sup> SSA Section 1853(b)(1)(B).

<sup>13</sup> See, CMS Fact Sheet: 2021 Medicare Advantage and Part D Advance Notice Part II, <https://www.cms.gov/newsroom/fact-sheets/2021-medicare-advantage-and-part-d-advance-notice-part-ii-fact-sheet>.

<sup>14</sup> Medicare Part C and D Annual Calendar, <https://www.cms.gov/files/document/2021annualcalendarfinal02112020v2pdf.pdf>.

per-person direct subsidy payments, adjusted for health risk and beneficiary premiums, but also low-income subsidies (to help cover cost-sharing for low-income enrollees), and projected reinsurance payments.<sup>15</sup>

Because MA and Part D plans are paid on a capitated basis and assume risk, plan sponsors have an incentive to constrain costs, for example, by providing more efficient health care and reducing unnecessary or harmful care. Additionally, plans may negotiate with providers, hospitals, or drug manufacturers to reduce the prices they pay to entities in their networks. Plans may also use other management techniques to reduce costs. For example, MA plan enrollees may be required to see a primary care physician before being referred to a specialist. Under Part D, enrollees may be required to try a less expensive drug or service before being covered for a more expensive one (i.e., step therapy). Enrollees also may be required to seek a PA from a plan before receiving an item, service, or drug, as discussed below.

## Prior Authorization

Though primarily associated with private insurers, PA is used in original Medicare for certain hospital outpatient department services, repetitive scheduled non-emergency ambulance transportation, and selected pieces of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS).<sup>16</sup> Additionally, the HHS Secretary has authority to apply PA to other services, such as home infusion services,<sup>17</sup> spinal subluxation services,<sup>18</sup> and in certain cases, imaging services.<sup>19</sup> The regulatory definition of PA, as it applies to selected DMEPOS under original Medicare, is a “process through which a request for provisional affirmation of coverage is submitted to CMS or its contractors for review before the item is furnished to the beneficiary and before the claim is submitted for processing.”<sup>20</sup> The purpose of the PA requirements generally is to reduce expenditures, unnecessary utilization, and improper payments. A 2018 Government Accountability Office (GAO) Report found that PA used in original Medicare decreased program expenditures for items and services.<sup>21</sup> While PA reduced unnecessary utilization, the report also found that some DMEPOS suppliers experienced challenges in obtaining the necessary documentation from referring physicians to submit for the PA requests.

## Prior Authorization in Medicare Advantage

Prior authorization<sup>22</sup> for MA plans is described by HHS as a “process through which the physician or other health care provider is required to obtain advance approval from the plan that payment will be made for a service or item furnished to the enrollee. Unless specified otherwise with respect to a particular item or service, the enrollee is not responsible for obtaining (prior) authorization.”<sup>23</sup> To satisfy a PA

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<sup>15</sup> See also, CRS Report R40611, *Medicare Part D Prescription Drug Benefit*.

<sup>16</sup> Centers for Medicare & Medicaid Services, *Prior Authorization and Pre-Claim Review Initiatives*, <https://www.cms.gov/research-statistics-data-systems/medicare-fee-service-compliance-programs/prior-authorization-and-pre-claim-review-initiatives>

<sup>17</sup> SSA Section 1834(u)(4).

<sup>18</sup> SSA Section 1833(aa)(2).

<sup>19</sup> SSA Section 1833(aa)(2).

<sup>20</sup> 42 CFR Section 414.234.

<sup>21</sup> U.S. Government Accountability Office, *Medicare: CMS Should Take Action to Continue Prior Authorization Efforts to Reduce Spending*, GAO-18-341, April 2018, p. 1, <https://www.gao.gov/products/GAO-18-341>.

<sup>22</sup> Prior authorization issues within the context of the COVID-19 Public Health Emergency exceed the scope of this memorandum.

<sup>23</sup> Department of Health and Human Service, Centers for Medicare & Medicaid Services, *Publication 100-16 - Medicare*

requirement, a physician or health care provider must demonstrate compliance with coverage and payment rules before an item or service is provided to the beneficiary, rather than after. If a PA is denied, an individual, or his or her health care provider, may appeal the decision through a process that allows for multiple levels of review and appeal.<sup>24</sup> Prior authorization is a management technique that can reduce unnecessary care, potentially harmful care, improper payments, or expenditures. However, PA can be burdensome and costly to providers and patients, and it may have the potential to delay care or discourage beneficiaries from receiving care if an item or service is initially denied.

Medicare statutes, regulations, and program manuals specify requirements and limitations with respect to the use of PA by MA plans. Medicare Advantage plans, for example, are prohibited from implementing utilization management protocols (such as PA, referrals for specialist services, or step therapy) that create inappropriate barriers to needed care.<sup>25</sup> Each plan's PA and other utilization management policies are submitted to CMS and evaluated as part of the Plan Benefit Package (PBP) at the beginning of each June as part of the yearly contracting process.<sup>26</sup> Regardless of any PA policy, MA plans are required to provide coverage for emergency services that meet the statutory definition of an emergency.<sup>27</sup> In addition to these coverage-related requirements, MA plans are also subject to certain disclosure requirements. Plans are required to disclose specified information, in a clear, accurate, and standardized format, to each enrollee at the time of enrollment and yearly thereafter, including "rules regarding prior authorization or other review requirements that could result in nonpayment."<sup>28</sup> Program manuals provide greater detail with respect to disclosure requirements, such as the documents that are required to be available on the plan website (including utilization management and PA forms for beneficiaries and physicians)<sup>29</sup> and required components for the Summary of Benefits documents (which are to include a notation when a service requires a physician referral or prior authorization).<sup>30</sup> The Medicare Plan Finder on the Medicare.gov website also may indicate if advance plan approval is required for certain items or services. Plans also are required to provide information about the appeal processes to follow if an item or service is initially denied.<sup>31</sup>

While MA plans are not required to use PA policies, research indicates that 4 out of 5 MA enrollees in 2018 were in an MA plan that used them, and that PA policies were most often used with respect to DME or skilled nursing facility stays.<sup>32</sup> For MA plans that use PA policies, due to data limitations, it is difficult

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*Managed Care Manual*, Chapter 4 - Benefits and Beneficiary Protections, April 22, 2016, Section 110.1.1, <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs.html>.

<sup>24</sup> See also, Medicare Managed Care Appeals and Grievances, <https://www.cms.gov/Medicare/Appeals-and-Grievances/MMCAG/index.html>.

<sup>25</sup> Department of Health and Human Service, Centers for Medicare & Medicaid Services, *Publication 100-16 - Medicare Managed Care Manual*, Chapter 4 - Benefits and Beneficiary Protections, April 22, 2016, Section 110.1.1, <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs.html>.

<sup>26</sup> See CY2021 Medicare Part C and D Annual Calendar, p. 4, <https://www.hhs.gov/guidance/document/cy2021-medicare-parts-c-and-d-annual-calendar-1>.

<sup>27</sup> SSA Section 1852(d)(1)(E).

<sup>28</sup> SSA Section 1852(c)(1)(G). Regulations can be found at 42 CFR Section 422.111(b)(7).

<sup>29</sup> Department of Health and Human Services, Centers for Medicare & Medicaid Services, *Medicare Communication and Marketing Guidelines*, September 5, 2018, pp. 18-19, <https://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/FinalPartCMarketingGuidelines.html>. This guidance was updated per Kathryn A. Coleman and Amy K Larrick Chavez-Valdez, Centers for Medicare & Medicaid Services, Health Plan Management System memorandum, *Medicare Communications and Marketing Guidelines*, August 9, 2019, however the portions of the guidance pertaining to prior authorization were not changed.

<sup>30</sup> *Ibid.*, pp. 71-72.

<sup>31</sup> Centers for Medicare & Medicaid Services, *Appeals if you have a Medicare health plan*, <https://www.medicare.gov/claims-appeals/file-an-appeal/appeals-if-you-have-a-medicare-health-plan>.

<sup>32</sup> Gretchen Jacobson and Tricia Newman, *Prior Authorization in Medicare Advantage Plans: How Often is it Used?*, Henry J.

to quantify how often plan physicians request PAs for plan enrollees. A recent study attempted to compensate for the lack of MA data by using Part B claims data and estimating how often a PA policy would have applied, based on PA policies of a large MA plan.<sup>33</sup> The study found that 41% of original Medicare beneficiaries in the sample received at least one service per year that would have been subject to the plan's PA requirements, had those beneficiaries been enrolled in the MA plan. Another study examined rates of coverage denials in MA plans from 2014 through 2016.<sup>34</sup> The study found that of all of the prior authorizations and payment denials by the MA plans included in the study, enrollees and providers appealed 1% of those denials to the first level of appeal. Of those who appealed to the first level, 75% of those denials were overturned by the MA plans, and independent reviewers at higher levels of the appeal process overturned additional denials.<sup>35</sup> Study authors recommended, in part, greater oversight of MA plans with high overturn rates, or low appeal rates. In contrast, a consensus statement generated by representatives of provider and health plan organizations identified opportunities to improving PA by, in part, focusing on more selective application of PA policies, reviewing and adjusting PA policies that are no longer warranted, improving communication between plans, providers, and patients, and automating the PA process to encourage efficiency.<sup>36</sup>

Unlike Part D plans, as discussed below, MA plans do not have a secure electronic PA (ePA) requirement. A recent report by the Council for Affordable Quality Healthcare (CAQH)<sup>37</sup> examined adoption of electronic administrative transactions, such as ePA, in the health care industry overall (i.e., not specifically for MA). In CY2019 as reported in the 2020 publication, CAQH found that 21% of PAs were processed completely electronically (an 8 percentage point increase from the prior year), 34% of PAs were processed manually, by phone, fax, or e-mail, and 45% were processed using a combination of manual and electronic means.<sup>38</sup>

A 2019 CAQH report examined efforts to promote full automation of the PA process, including barriers to adoption.<sup>39</sup> For example, certain state rules specify that health insurance plans must use manual means to notify enrollees if a PA request is declined. Another barrier to full ePA adoption includes the lack of a

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Kaiser Family Foundation, Data Note, October 2018, <https://www.kff.org/medicare/issue-brief/prior-authorization-in-medicare-advantage-plans-how-often-is-it-used/>.

<sup>33</sup> Aaron L. Schwartz MD, PhD, Troyen A. Brennan MD, JD, MPH, and Dorothea J. Verbrugge, MD, et al., "Measuring the Scope of Prior Authorization Policies Applying Private Insurance Rules to Medicare Part B," *JAMA Health Forum*, May 18, 2021, <https://jamanetwork.com/journals/jama-health-forum/fullarticle/2780396>.

<sup>34</sup> Daniel R. Levinson, *Medicare Advantage Appeal Outcomes and Audit Findings Raise Concern About Service and Payment Denials*, Department of Health and Human Services, Office of Inspector General, OEI-09-16-00410, September 2018, <https://oig.hhs.gov/oei/reports/oei-09-16-00410.asp>. This study examined 24 million prior authorization requests that had been denied, along with 424 million payment requests for services that had already been provided to beneficiaries and for which payment had been denied.

<sup>35</sup> Similar results (74% of appeals overturned or partially overturned) were found in an OIG study on Medicare Part D plans. Suzanne Murrin, *Some Medicare Part D Beneficiaries Face Avoidable Extra Steps That Can Delay or Prevent Access to Prescription Drugs*, Department of Health and Human Services Office of the Inspector General, OEI-09-16-00411, September 2019, <https://oig.hhs.gov/oei/reports/oei-09-16-00411.asp>.

<sup>36</sup> Consensus Statement on Improving the Prior Authorization Process, <https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/public/arc-public/prior-authorization-consensus-statement.pdf>.

<sup>37</sup> CAQH is "a non-profit alliance of health plans and related associations." They "develop and implement shared, industry-wide initiatives to eliminate long-term business inefficiencies." Members include AHIP, Aetna, Anthem, BlueCross BlueShield, Cigna, Humana, Kaiser, and UnitedHealth, <https://www.caqh.org/about/about-caqh>.

<sup>38</sup> These data are based on a survey of medical health plans and dental health plans "represent[ing] 167 million covered lives, or 51% of the United States enrolled population." *2020 CAQH Index: Closing the Gap: The Industry Continues to Improve, But Opportunities for Automation Remain*, p. 16, <https://www.caqh.org/explorations/caqh-index-report-0>.

<sup>39</sup> CAQH, *Moving Forward: Building Momentum for End-to-End Automation of the Prior Authorization Process*, 2019, <https://www.caqh.org/about/press-release/caqh-core-white-paper-outlines-plan-accelerate-automation-prior-authorization>.

federal standard for attachments and clinical documentation; PAs, unlike other administrative electronic transactions, require the attachment of clinical data from the medical record, but many software companies are hesitant to design PA software that allows for attachments lest they be required to redo the software to conform to subsequently published federal requirements. The report also points to a lack of consistent data content (such as maximum timeframes for plan responses to PA requests, requirements to specify next steps or the need for additional information) as barriers to ePA adoption, and indicates that switching to an entirely electronic PA process could save providers money and positively affect patient care. However, there may be a cost to administering or upgrading to a new system with ePA capabilities.

### **Prior Authorization in Medicare Part D<sup>40</sup>**

As discussed above, there is no central formulary in Part D, although each plan must maintain a detailed formulary, which is a list of drugs covered by the plan and the terms under which they are covered.<sup>41</sup> Part D plan formularies must include at least two drugs in each class and category, and substantially all drugs in six protected classes.<sup>42</sup> Part D plan sponsors must use Pharmacy and Therapeutics (P&T) Committees to develop formularies based on scientific evidence and standards of practice. Plans manage beneficiary access to drugs through such formulary utilization tools as requiring a beneficiary to obtain PA from a plan before filling a prescription, setting quantity limits on prescriptions, and instituting step therapy. Part D plans are encouraged to consistently utilize PA for drugs prescribed for non-Part D covered uses and to ensure that Part D drugs are only prescribed when medically appropriate. CMS reviews plan formularies each year to ensure they include the required mix of drugs and do not discriminate against enrollees based on health conditions.

Part D enrollees have the right to appeal drug coverage determinations, file grievances against plan sponsors, and file complaints regarding quality of care. Part D plan sponsors must provide enrollees with written information about their rights, and institute standard and expedited procedures for addressing coverage issues.<sup>43</sup> Coverage issues can include questions about coverage determinations, which includes decisions (whether an approval or denial) made by a plan sponsor with regard to covered benefits. A drug approved or denied through prior authorization constitutes a coverage determination, subject to all applicable coverage determination standards, timelines, and requirements.<sup>44</sup>

Disclosure requirements in Medicare program manuals (discussed above in relation to beneficiary education and availability of information in MA plans) also apply to Part D plans. In addition, Part D plans must provide access to toll-free call centers staffed with live customer representatives who are available during normal business hours to respond to questions about coverage determinations, exceptions, PAs, and appeals.<sup>45</sup>

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<sup>40</sup> As S. 3018 does not amend the Part D provisions of the Social Security Act; the description of PA under Part D plans in this memorandum is an abbreviated summary of the relevant policies.

<sup>41</sup> CMS, *Medicare Prescription Drug Benefit Manual*, Chapter 6, “Part D Drugs and Formulary Requirements,” Section 30.2.1, Rev. January 15, 2016, <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals>. Part D sponsors may use existing drug classification systems, such as those from U.S. Pharmacopeia (USP) and American Hospital Formulary Service (AHFS), or create their own.

<sup>42</sup> *Ibid.*, p. 28.

<sup>43</sup> CMS, *Medicare Appeals*, <https://www.medicare.gov/Pubs/pdf/11525-Medicare-Appeals.pdf>.

<sup>44</sup> CMS, “Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance,” Sec. 40.2, Effective January 1, 2020.” Available at <https://www.cms.gov/Medicare/Appeals-and-Grievances/MMCAG/Downloads/Parts-C-and-D-Enrollee-Grievances-Organization-Coverage-Determinations-and-Appeals-Guidance.pdf>. CMS, See also *Medicare Prescription Drug Benefit Manual*, Chapter 6, “Part D Drugs and Formulary Requirements,” Section 20.2.2, Rev. January 15, 2016.

<sup>45</sup> *Ibid.*, p 23.



Part D plans must also meet requirements for electronic or e-prescribing, which is defined by CMS as the transmission using electronic media, of prescription or prescription-related information between a prescriber, dispenser, pharmacy benefit manager, or health plan, either directly or through an intermediary, including an e-prescribing network.<sup>46</sup> E-prescribing allows insurers, prescribers, and pharmacies to quickly exchange information about prescribed drugs, patient medical histories, and other pertinent information.

CMS regulations and contract provisions require Part D plan sponsors to utilize e-prescribing systems that allow for transmission of information about enrollee eligibility, plan benefits (including drugs on the plan formulary and formulary requirements including any prior authorization requirements), the drug being prescribed or dispensed and other drugs listed in the medication history, and the availability of lower cost, therapeutically appropriate alternatives (if any) for the drug prescribed.<sup>47</sup> Part D plans must base their e-prescribing programs on standards developed by the National Council for Prescription Drug Programs (NCPDP SCRIPT). The NCPDP is an accredited standards development organization.<sup>48</sup>

The Part D foundational e-prescribing regulations were published in 2005.<sup>49</sup> The regulations have been updated a number of times to incorporate new data and revisions to the NCPDP system, or in response to the addition of statutory requirements.<sup>50</sup> In May 2019, CMS issued final rules requiring Part D sponsors, no later than January 1, 2021, to implement one or more electronic real-time benefit tools (RTBT) that include secure electronic transmission of prior authorization (ePA) requests from prescription drug prescribers, in addition to responses from PDP or MA-PD plans to the prescribers.<sup>51</sup> Implementation of the final rule was later delayed to March 2021.<sup>52</sup>

## Summary of S. 3018, the “Improving Seniors’ Timely Access to Care Act of 2020”

### Section 1. Short Title.

The act is cited as the “Improving Seniors’ Timely Access to Care Act of 2020”.

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<sup>46</sup> 42 C.F.R. §423.159.

<sup>47</sup> See 42 C.F.R. §423.505(b)(6) for Part D contract requirements. See 42 CFR §423.160 for CMS standards for electronic prescribing. See also Social Security Act 1860D-4(e).

<sup>48</sup> NCPDP, “Who We Are,” <https://www.ncdp.org/Who-We-Are.aspx>.

<sup>49</sup> CMS, *Federal Register*, “Medicare Program; E-Prescribing and the Prescription Drug Program; Final Rule,” November 7, 2005, p. 67568, <https://www.gpo.gov/fdsys/pkg/FR-2005-11-07/pdf/05-22026.pdf>.

<sup>50</sup> The “Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act” (the SUPPORT Act) included requirements to upgrade e-prescribing standards to ensure secure electronic prior authorization request and response transmissions. A subsequent proposed rule, published June 19, 2019, specified the technical standard to be used for the ePA transactions. HHS, “Medicare Program: Secure Electronic Prior Authorization for Medicare Part D,” 84 *Federal Register* 28450, June 19, 2019, <https://www.federalregister.gov/documents/2019/06/19/2019-13028/medicare-program-secure-electronic-prior-authorization-for-medicare-part-d>.

<sup>51</sup> 42 C.F.R. 423.160(b)(7); SSA Section 1860D-4(e). Though MA does not have a separate electronic prescribing program, an MA provision at SSA Section 1857(j)(7) promotes e-prescribing by allowing a separate payment from MA-PD plans to participating physicians that prescribe drugs in accordance with the electronic prescription drug program under Section 1860D-4(e).

<sup>52</sup> CMS, “Medicare Program; Secure Electronic Prior Authorization for Medicare Part D Program; Delay in Effective Date,” 86 *Federal Register*, February 2, 2021, p. 7813; <https://www.federalregister.gov/documents/2021/02/02/2021-02181/medicare-program-secure-electronic-prior-authorization-for-medicare-part-d-program-delay-in>.

## Section 2. Establishing Requirements with Respect to the Use of Prior Authorization under Medicare Advantage Plans.

### Provision

S. 3018 would amend SSA Section 1852 by adding a new section that would require MA plans to establish electronic prior authorization programs, meet specified transparency requirements, meet beneficiary protection standards, and require the promulgation of rules and publication of reports.

### *Electronic Prior Authorization Program.*

Starting the second plan year after enactment, this provision would require MA plans that impose applicable PA requirements to establish electronic PA processes that provide for the secure electronic transmission of both PA requests from health care professionals to the MA plan, as well as the corresponding response from the plan to the professionals. With respect to the electronic PA request, the transmission would be required to be capable of including clinical information necessary to provide evidence of medical necessity. The provision would not allow facsimiles, proprietary payer portals that do not meet standards specified by the HHS Secretary, nor electronic forms to qualify as secure electronic transmissions.

The MA plans' electronic PA program would be required to comply with technical standards adopted by the HHS Secretary. In developing the technical standards, the HHS Secretary would be required to consult with standard-setting organizations determined appropriate by the HHS Secretary, as well as health care professionals, MA organizations, and health information technology software vendors. In adopting the standards, the HHS Secretary would be required to ensure that the electronic transmissions support attachments containing applicable clinical information. The HHS Secretary would also be required to prioritize the adoption of standards that support integration of the electronic PA program with interoperable health information technology certified under a program of voluntary certification kept or organized by the National Coordinator of Health Information Technology.<sup>53</sup> The standards established by the HHS Secretary would also be required to include a standard for transmission of attachments, and data elements and operating rules for the transmission, consistent with health care industry standards.

The electronic PA program would be required to provide “real-time decisions” with respect to specified PA requests if the requests contained all the documentation used by plans for making coverage determinations, as described in the transparency requirements below. The HHS Secretary would be required to define “real-time decisions” taking into account current medical practice, technology, health care industry standards, and other relevant information and factors to ensure the accurate and timely furnishing of items and services to individuals. The HHS Secretary would also be required to update the definition of “real-time decisions” not less often than once every two years, taking into account changes in medical practice, technology, health care industry standards, and other relevant information, such as data provided to the HHS Secretary as part of the transparency requirements, described below.

Requests subject to real-time decisions would be those that the HHS Secretary identified as requests for items and services that were routinely approved by the plan; the HHS Secretary would be required to identify those items and services by no later than the first Monday of April prior to the calendar year concerned, and would apply for two plan years, and be updated for each subsequent two-year period. In identifying PA requests that are routinely approved, the HHS Secretary would be required to use

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<sup>53</sup> The National Coordinator of Health Information Technology is an office within the Office of the Secretary of Health and Human Services. They are the “principal federal entity charged with coordination of nationwide efforts to implement and use the most advanced health information technology and the electronic exchange of health information.” See, *About ONC*, <https://www.healthit.gov/topic/about-onc>.

information provided by MA plans as part of the transparency requirements described below, if available, and also would be required to issue a request for information from Medicare Advantage plans, providers, suppliers, patient advocacy organizations, and other stakeholders for purposes of identifying specified PA requests. The Secretary would be required to use notice and comment rulemaking, which may include use of the annual call letter process, when establishing and updating the definition of real-time decision, and when identifying applicable items and services for the initial and subsequent 2-year periods.

### *Transparency Requirements.*

S. 3018 would require MA plans that impose applicable PA requirements to adhere to specified transparency requirements. MA plans would be required to submit the following information to the HHS Secretary annually:

1. A list of all covered Medicare Parts A and B benefits that are subject to a PA requirement;
2. The percentage of PA requests approved during the previous year by the plan in an initial determination by item and service;
3. The percentage of PA requests that were initially denied and that were subsequently appealed in any manner, and the percentage of appealed PA requests that were overturned, by item and service, broken down by each stage of appeal including judicial review MA plans may include information regarding the initial denials due to the request submissions not meeting clinical evidence standards;
4. The percentage of PA requests that were denied and the percentage of the total number of denied requests that were denied as a result of decision support technology or other decision-making tools;
5. The average and median amount of time (in hours) that elapsed during the previous plan year between the submission of the PA request and the determination by the plan, by item and service, but excluding any request that did not contain all the information the plan required;
6. Descriptions of each occurrence during the previous plan year in which the plan made a determination to approve or deny an item or service in the case where a provider furnished an additional or differing item or service during the preoperative period of a surgical or otherwise invasive procedure that such provider determined was medically necessary;
7. A disclosure and description of any software decision-making tools the plan uses with respect to PA requests; and
8. Such other information as the HHS Secretary determines appropriate.

In addition to submitting information to the HHS Secretary, each plan would be required to provide specific information to prospective providers or suppliers, providers and suppliers who have entered into contract with the MA plan, and to plan enrollees. For each provider or supplier seeking to enter into contract with the MA plan, the plan is required to provide a list of all Medicare covered items and services subject to PA and any policies or procedures used for making PA determinations. For each provider or supplier who has a contract with the MA plan, the plan is required to provide access to the criteria used for making determinations, including an itemization of the medical or other documentation required to be submitted by the provider or supplier, excluding proprietary information. For each enrollee subject to PA, MA plans must provide access to the criteria for making determinations, excluding proprietary information. The HHS Secretary would be required to promulgate regulations regarding the establishment of criteria that plans would use for making determinations and how providers, suppliers, and beneficiaries could access those criteria.

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The Medicare Payment Advisory Committee would be required to submit a report to Congress, which would include a descriptive analysis of the use of prior authorization. As appropriate, the report would be required to include statistics on the frequency of appeals and overturned decisions, and would be required to include recommendations, as appropriate, on any improvement that to the MA electronic PA program. The report is required to be submitted not later than 3 years after the date information is first submitted to the Secretary as part of the transparency requirements.

### ***Beneficiary Protection Standards.***

S. 3018 would require the HHS Secretary to specify requirements for use of PA by MA plans through notice and comment rulemaking, to ensure the following:

1. Adoption of transparent programs developed in consultation with contracted providers and suppliers that allow for the modification of such PA requirements based on the performance of providers and suppliers with respect to adherence to evidence-based medical guidelines and other quality criteria;
2. Requirements for annual reviews of items and services for which prior authorization requirements are imposed under the plans, through a process that takes into account input from participating contracted providers and suppliers and is based on analysis of past PA requests and current coverage and clinical criteria;
3. Continuity of care for individuals transitioning to, or between, coverage under the plan in order to minimize any disruption to ongoing treatment attributable to the PA requirements of the plan;
4. Requirements that the MA plan makes timely PA determinations, provides rationale for denials, and ensures requests are reviewed by qualified medical personnel; and
5. Plans provide information on the appeals process to a beneficiary when denying any request for PA.

### ***Definition of “Applicable Item or Service.”***

The term “applicable item or service” would be defined, with respect to an MA plan, as any item or service for which benefits are available under the plan, other than a covered Part D drug.

### ***Report to Congress***

The HHS Secretary would be required to submit a series of reports to Congress evaluating the implementation of the requirements of the new subsection to SSA Section 1852 created by this Act, analyzing issues faced by MA plans in implementing the requirements, and descriptions of the information submitted under the transparency requirements with respect to (a) for the first report, the second plan year, and (b) for subsequent reports, the two full plan years preceding the date of submission of the report. The HHS Secretary would be required to submit the first report not later than the end of the second plan year beginning on or after the date of enactment, and biennially thereafter through the date that is 10 years after enactment.

### ***Clarification***

S. 3018 would clarify that any decision made with respect to a PA request for a service is a part of the MA plan’s procedure for determining whether an individual enrolled in the plan is entitled to receive a health service.

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