AI-INSURANCE AS A REGULATORY MECHANISM FOR AI-BASED CLAIMS DENIALS UNDER MEDICARE ADVANTAGE

*Jessica N. Creekmore**

INTRODUCTION

The Centers for Medicare and Medicaid (CMS) derives its broad authority to promulgate rules to manage the Medicare Advantage program from the Department of Health and Human Services (HHS). Currently, there is no federal legislation or regulatory scheme aimed at regulating utilization of artificial intelligence (AI) by Medicare Advantage Contractors (MACs). MACs who employ AI are facing liability for damages associated with AI utilization, and these MACs are fully responsible for this liability. The premise of this Comment is two-fold: (1) to suggest that requiring insurance to cover AI-related damages is an acceptable regulatory mechanism for MACs, and (2) CMS has federal authority to mandate this requirement.

To explore this proposal, Part I of this Comment covers the history and current state of Medicare Advantage. Part II reviews the reason MACs use prior authorization and how contractors are employing artificial intelligence technology to make medical coverage determinations. Part III provides a high-level summary of the current state of AI regulation, remedies for denied coverage, and insurance as a regulatory mechanism. Part IV details CMS's express statutory authority to dictate MACs eligibility requirements and how statutory interpretation, relying on interpretative theory and tools, further supports this understanding of the law. This section also reviews challenges to CMS's authority to enact regulations based on historical *Chevron* deference and challenges now without that administrative deference. Part V concludes by stating that CMS has the necessary authority to mandate insurance as an eligibility requirement for MACs. CMS mandated AI-insurance, for those MACs who choose to employ artificial intelligence tools, would hold MAC plans accountable to statutory requirements and appropriate medical coverage determinations.

* I would like to thank Christine Farmer, Esq. for her insight into AI-based claims denials, which this Comment proposes to address. I would also like to thank my husband and son for their unwavering support of my law school journey and career development.

I. MEDICARE ADVANTAGE

A. History of Medicare

In the 1960s, due to a large gap in the social security program and limited accessibility of private insurance, the elderly who faced decreasing income due to aging and simultaneously rising health care costs experienced inadequate healthcare coverage.[1] Those with the monetary means to pay for private insurance faced financial ruin if they encountered a significant illness or diagnosis.[2] In 1965, President Lyndon B. Johnson signed into law the Social Security Act Amendments to create the Medicare program.[3] The Health Insurance for the Aged Act initially targeted individuals aged sixty-five and older and provided two health insurance plan options: (1) Part A insurance coverage for hospitalization and related care,[4] and (2) Part B insurance coverage for physician's services.[5] Later, Parts C and D were added for bundled coverage by private insurance companies and for prescriptt-ion drug coverage, respectively.[6]

B. Medicare vs. Medicare Advantage

Today, Medicare is managed through the Centers for Medicare and Medicaid Services, which falls under the Department of Health and Human Services.[7] The Medicare program has undergone multiple revisions and expansions to provide affordable means to secure healthcare for eligible individuals.[8] Traditional Medicare is a fee-for-service plan that includes hospital insurance and outpatient physician medical insurance.[9] A separate Medicare plan can be purchased for pharmaceutical drug coverage.[10] As part of the Balanced Budget Act of 1997, Part C, Medicare Advantage (MA), was created to offer Medicare coverage through private insurance companies that contract with CMS and includes Parts A, B, and D.[11]

MA plans "must cover all medically necessary services that Original Medicare covers," follow all traditional Medicare rules, and beneficiaries are

1. *History of SSA During the Johnson Administration 1963-1968*, SOC. SEC., https://www.ssa.gov/history/ssa/lbjmedicare1.html (last visited Mar. 10, 2026).
2. *Id.*
3. *Id.*; 42 U.S.C. §§ 401-426 (1965).
4. *History of SSA During the Johnson Administration 1963-1968*, *supra* note 1; §§ 401-426.
5. *History of SSA During the Johnson Administration 1963-1968*, *supra* note 1.
6. *History*, CMS.GOV (Aug. 18, 2025, at 16:39 ET), https://www.cms.gov/about-cms/who-we-are/history.
7. *CMS Organization Chart*, CMS.GOV (Apr. 22, 2025), https://www.cms.gov/about-cms/agency-information/cmsleadership/downloads/cms_organizational_chart.pdf.
8. *History*, *supra* note 6.
9. *Understanding Medicare Advantage Plans*, MEDICARE.GOV 1, https://www.medicare.gov/publications/12026-Understanding-Medicare-Advantage-Plans.pdf (last visited Mar. 10, 2026).
10. *Id.* at 2.
11. *Health Plans – General Information*, CMS.GOV (Sep. 10, 2024, at 18:21 ET), https://www.cms.gov/medicare/enrollment-renewal/health-plans.

entitled to the same rights and protections as traditional Medicare beneficiaries.[12] As a result of the CMS contract and payment system, MACs can offer extra benefits, such as limits on out-of-pocket spending, dental, vision, and hearing coverage.[13] MA plans are only offered by a few select insurance firms, and UnitedHealthcare and Humana alone cover nearly half of those beneficiaries enrolled.[14]

There are other notable differences when comparing Medicare and Medicare Advantage plans. MACs require beneficiaries to use in-network providers, obtain referrals for specialty providers, and usually require prior authorization of major services and medications before agreeing to pay for those services.[15] Medical coverage determinations are the decisions by the MA plan to cover or deny payment of a requested service or medication.[16]

II. PRIOR AUTHORIZATION DENIALS BY AI ALGORITHMS

A. Medical Coverage Determinations

Medicare Advantage plans, unlike traditional Medicare plans, use two primary cost management tools: (1) limited network providers and services, and (2) prior authorization (PA) of providers and services.[17] Prior authorization is used by MACs to ensure that healthcare is medically indicated and necessary prior to agreeing to pay for it.[18] By keeping payments for only medically necessary services, insurers can control and contain their spending for policy holders. Prior authorization is generally required for "expensive services, such as skilled nursing facility stays (99%), Part B drugs (98%), inpatient hospital stays (acute: 98%; psychiatric: 93%), and outpatient psychiatric services (82%)," along with other benefits such as dental, eye, and hearing services.[19] In 2022, approximately 46.2 million prior authorization requests were submitted, with 42.7 million approved,

12. *Understanding Medicare Advantage Plans*, *supra* note 9, at 4; 42 C.F.R. § 422.101(a)-(b) (2024).

13. MEDPAC, *The Medicare Advantage Program: Status Report in* REPORT TO THE CONGRESS: MEDICARE PAYMENT POLICY 357, 357-411 (2024), https://www.medpac.gov/wp-content/uploads/2024/03/Mar24_Ch12_MedPAC_Report_To_Congress_SEC-1.pdf; *see* Phillips v. Kaiser Found. Health Plan, Inc., 953 F. Supp. 2d 1078, 1082 (N.D. Cal. 2011).

14. Meredith Freed et al., *Medicare Advantage in 2024: Enrollment Update and Key Trends*, KFF (Aug. 8, 2024), https://www.kff.org/medicare/issue-brief/medicare-advantage-in-2024-enrollment-update-and-key-trends/.

15. *Understanding Medicare Advantage Plans*, *supra* note 9, at 2-3.

16. *See id.* at 4.

17. Freed et al., *supra* note 14.

18. Jeannie F. Biniek et al., *Medicare Advantage Insurers Made Nearly 50 Million Prior Authorization Determinations in 2023*, KFF (Jan. 28, 2025), https://www.kff.org/medicare/issue-brief/use-of-prior-authorization-in-medicare-advantage-exceeded-46-million-requests-in-2022/.

19. Meredith Freed et al., *Medicare Advantage in 2024: Premiums, Out-of-Pocket Limits, Supplemental Benefits, and Prior Authorization*, KFF (Aug. 8, 2024), https://www.kff.org/medicare/medicare-advantage-in-2024-premiums-out-of-pocket-limits-supplemental-benefits-and-prior-authorization/.

and 3.4 million fully or partially denied.[20] MA plans must "make medical determinations based on…whether the provision of items or services is reasonable, …the enrollee's medical history (for example, diagnoses, conditions, functional status), physician recommendations, and clinical notes."[21] This language is well understood to mean that beneficiaries will get an individualized medical review based on their recent treatment and pertinent medical history prior to a medical coverage determination.[22] MA organizations are prohibited from discriminating when making coverage determinations.[23]

The requirement for prior authorizations, however, has become a "nightmare," and thus prior authorization reform is one priority of the American Medical Association (AMA)[24] and a rising priority for Congress.[25] It has long been demonstrated that requiring prior authorizations that result in partially or fully denied care causes several barriers to receiving care.[26] The prior authorization process is frequently described as an administratively burdensome and costly process, which increases delays in care, contributes to significant patient safety events, and takes physician's time away from other patients.[27] Every year the AMA conducts a physician survey "[t]o assess the ongoing impact the PA process has on patients, physicians, employers, and overall health care spending."[28] In addition to validating patient safety concerns, the survey also revealed that prior authorization leads to "unnecessary spending [such as] additional office visits, unanticipated hospital stays, and patients regularly paying out-of-pocket for care."[29] The relatively new use of artificial intelligence (AI) by insurers during the prior authorization process further complicates the already existing issues.[30]

---

20. Biniek et al, *supra* note 18.

21. 42 C.F.R. § 422.101(c) (2024).

22. *See* United States *ex rel.* Nedza v. Am. Imaging Mgmt., Inc., 2020 WL 1469448, at *2 (N.D. Ill. 2020) ("Applicable Medicare rules require that any pre-authorization process must allow for 'individual medical necessity determinations' for requested treatments.").

23. 42 C.F.R. § 422.110(a) (with the exception of the amendments appearing at 89 FR 80055).

24. Andis Robeznieks, *Once Just a Burden, Prior Authorization Has Become a Nightmare*, AM. MED. ASS'N (May 3, 2023), https://www.ama-assn.org/practice-management/prior-authorization/once-just-burden-prior-authorization-has-become-nightmare.

25. Doctor Knows Best Act, H.R. 6230, 118th Cong. (2023); Medicare Advantage Consumer Protection and Transparency Act, H.R. 5854, 118th Cong. § 4 (2023); GOLD CARD Act, H.R. 4968, 118th Cong. (2023); Promoting Transparency & Healthy Competition in Medicare Act, H.R. 3282 (C)(ix), 118th Cong. (2023); Reducing Medically Unnecessary Delays in Care Act, H.R. 5213, 118th Cong. (2023).

26. Biniek et al, *supra* note 18; *2024 AMA Prior Authorization Physician Survey*, AM. MED. ASS'N (2024), https://www.ama-assn.org/system/files/prior-authorization-survey.pdf.

27. Robeznieks, *supra* note 24; Eugene Yang & Susan Yang, *Prior Authorization: Overwhelming Burden and Critical Need for Reform*, 2 JACC: CASE REPS., 1466, 1466 (2020); *2024 AMA Prior Authorization Physician Survey*, *supra* note 26; Letter from Ryan Mire, President, Am. Coll. of Physicians, to Majority and Minority Leaders of Cong. (Jan. 18, 2023) (on file with author), https://www.acponline.org/sites/default/files/acp-policy-library/letters/acp_letter_to_congressional_leaders_regarding_priorities_for_118th_congress_2023.pdf.

28. *2024 AMA Prior Authorization Physician Survey*, *supra* note 26.

29. *Id.* (alteration in original).

30. *See* Biniek et al., *supra* note 18.

B. Artificial Intelligence for Prior Authorization

The insurance industry is founded on big data and has a long history of using predictive analytics.[31] AI "decision-making tools have several applications in the health care field, from diagnosing patients to assisting commercial insurance brokers in the Medicare shopping process."[32] Prior authorization review by health insurance companies is prime real estate for AI-enabled processes. Prior authorization review is a high volume, complex, and inefficient process that requires sophisticated critical thinking.[33] AI can generate medical coverage determinations faster than human determinations, addressing a prevalent barrier in the industry—delays in approving medical coverage.[34] Support for using enhanced technology like AI for prior authorization is multifactorial, with the ultimate goal of enhancing efficiency and quality, controlling costs, and ensuring personalized access to care.[35]

However, AI-enabled prior authorization review has proven that the lack of human oversight required for prior authorization has real consequences.[36] Data feeding AI algorithms are "embedded with societal bias including structural racism," and clinicians at the bedside are usually aware of important individual socioeconomic factors that are not found in the medical record for algorithm use.[37] Racial discrimination resulting from AI-based decision-making models, while not discussed specifically here, is recognized as occurring with "surprising frequency."[38] Notably, however, Medicare Advantage plans that utilize AI for medical coverage determinations demonstrate errors intrinsic to AI—wrongful denial of needed medical treatment.[39] Medicare Advantage plans must provide the same level of coverage as traditional Medicare, and that does not always occur when AI algorithms wrongfully deny claims.[40]

C. AI-Denied Medical Coverage Determinations

In 2022, the Center for Medicare Advocacy issued a Special Report focused on three things: (1) "[t]o what extent do AI-powered decision-making

---

31. Michelle Mello & Sherri Rose, *Denial—Artificial Intelligence Tools and Health Insurance Coverage Decisions*, 3 JAMA HEALTH F., Mar. 7, 2024, at 1, 1-3.

32. Lyla Saxena, *The Role of AI-Powered Decision-Making Technology in Medicare Coverage Determinations,* CTR. FOR MEDICARE ADVOC. 1 (Jan. 2022), https://medicareadvocacy.org/wp-content/uploads/2022/01/AI-Tools-In-Medicare.pdf.

33. Mello & Rose, *supra* note 31, at 1.

34. *See id.*

35. Fazal Khan, *Regulating the Revolution: A Legal Roadmap to Optimizing AI in Healthcare*, 25 MINN. J.L. SCI. & TECH. 49, 55-57 (2023).

36. Mello & Rose, *supra* note 31, at 1.

37. *Id.* at 2; *see also* Khan, *supra* note 35, at 64 ("A significant concern is that black box algorithms may silently entrench societal biases and discriminate against marginalized groups.").

38. Sharona Hoffman & Andy Podgurski, *Artificial Intelligence and Discrimination in Health Care*, 19 YALE J. HEALTH POL'Y L. & ETHICS 1, 1 (2020).

39. Mello & Rose, *supra* note 31, at 1.

40. *Id.*

tools…supplant, rather than supplement, clinical decision making," (2) how prevalent AI tools are in Medicare, and (3) if the algorithm uses a more restrictive criteria for coverage determinations than Medicare law.[41] The research suggests the responsible clinical reviewer who utilizes an AI algorithm for a medical coverage determination contends to make the final coverage decision; however, that reviewer nearly always uses the automated decision of the AI algorithm itself, thereby supplanting versus supplementing the individualized review that is mandated by CMS.[42]

It was further noted that "AI-powered decision-making tools make benefits determinations using added eligibility criteria not required by law."[43] AI algorithms are prompting more restrictive guidelines for medical coverage than what Medicare coverage guidelines mandate, ultimately leading to unlawful coverage denial.[44] The research suggests that challenges to AI-tools for medical coverage determinations violate "constitutional or statutory due process rights…[and] federal or state notice requirements."[45] Algorithms for medical coverage have resulted in denied care that is not accurate, unlawful, ambiguous in rationale, and does not align with the clinical recommendations of either the physicians at the bedside or CMS.[46]

In March of 2023, STAT News released a story highlighting "[h]ow Medicare Advantage plans use [AI] algorithms to cut care for seniors in need" and the deleterious effects of "unregulated predictive algorithms."[47] They highlighted the story of an eighty-five year old woman who spent down her life savings when her Medicare Advantage plan decided she no longer needed skilled nursing care for a shattered left shoulder, despite the fact that she could not dress herself, go to the bathroom alone, or even push a walker.[48] Her Medicare Advantage plan, relying on the AI algorithm it used, predicted that she should recover 16.6 days into skill nursing treatment, and stopped payment on day 17.[49] She was not recovered by day 17.[50] Over a year later and thousands of dollars spent, a federal judge declared the Medicare Advantage plan's AI determination to be speculative and thereby her MA plan owed thousands of dollars in reimbursement for her additional three weeks of treatment.[51] This story is one of many, where patients are

41. Saxena, *supra* note 32 at 2; 42 C.F.R. §§ 422.101(b)(1)-(2) (2023) ("Each MA organization must meet the following requirements:…(b) comply with- (1) CMS's national coverage determinations; (2) General coverage and benefit conditions included in Traditional Medicare laws.").

42. Saxena, *supra* note 32, at 4-5.

43. *Id.* at 7.

44. *See id.* at 7-8.

45. *Id.* at 8.

46. Mello & Rose, *supra* note 31, at 1-2.

47. Casey Ross & Bob Herman, *Denied by AI: How Medicare Advantage Plans Use Algorithms to Cut off Care for Seniors in Need*, STAT10 NEWS (Mar. 13, 2023), https://www.statnews.com/2023/03/13/medicare-advantage-plans-denial-artificial-intelligence/.

48. *Id.*

49. *Id.*

50. *Id.*

51. *Id.*

not receiving the care they need because they cannot afford it, the required care is delayed until a financing method is found, or an appeal to the plan overturns a decision.

The STAT News investigation also noted that while some AI models that assist in detecting and diagnosing diseases are subject to regulation by the Food and Drug Administration (FDA), AI algorithms utilized by insurance companies to determine if the treatment of those diseases is covered are not subject to the same regulation.[52] Further, once coverage is denied, beneficiaries and physicians are met with little to no explanation of the decision since the algorithm is "proprietary," leading to "black box" excuses.[53] As a result of the increasing utilization of AI and inappropriately denied medical claims, the alarms are sounding and litigation is underway.[54]

Between 2023 and 2024, four class action lawsuits were filed against large Medicare Advantage insurers: Cigna, Humana, UnitedHealth, and Blue Shield California (member of Blue Cross Blue Shield association).[55] Each claim alleges the insurance company utilized a proprietary AI algorithm to review prior authorizations, foregoing an individualized medical review of each beneficiary's claim, resulting in large inappropriate denials of care, patient harm, and lost money.[56] Causes of action included: violations of implied covenant of good faith and fair dealing, unjust enrichment, violation of unfair competition laws, breach of contract, and unfair and deceptive insurance practices or insurance bad faith.[57] Nonetheless, it is well documented that "Augmented Intelligence (AI) systems have the power to transform health care by harnessing the promise of artificial

52. *Id.*

53. *Id.*; Anat Lior, *Insuring AI: The Role of Insurance in Artificial Intelligence Regulation*, 35 HARV. J. L. & TECH., 467, 479 (2022) ("The black-box issue refers to the fact that the decision-making process of an AI entity cannot be evaluated while the decision is being made, nor in the aftermath of a decision.").

54. *See generally* Jake Johnson, *Biden Urged to Crack Down on 'Terrifying' Use of AI by Medicare Advantage Insurers*, COMMON DREAMS (Mar. 27, 2023), https://www.commondreams.org/news/biden-ai-medicare-advantage ("This barbaric practice must end…. We're calling on President Biden and the [Centers for Medicare and Medicaid Services] to stop this practice immediately."); Susan Jaffe, *Feds Rein in Use of Predictive Software that Limits Care for Medicare Advantage Patients*, KFF HEALTH NEWS (Oct. 5, 2023), https://kffhealthnews.org/news/article/biden-administration-software-algorithms-medicare-advantage/ ("The federal government will try to even the playing field next year, when the Centers for Medicare & Medicaid Services begins restricting how Medicare Advantage plans use predictive technology tools to make some coverage decisions.").

55. Class Action Complaint at 1, Kisting-Leung v. Cigna Corp., 780 F. Supp. 3d 985 (E.D. Cal. 2025) [hereinafter *Kisting-Leung* Complaint]; Class Action Complaint at 1, Jong v. Blue Shield of Cal., No. 24CV068627 (Cal. Super. Ct. Mar. 28, 2024) [hereinafter *Jong* Complaint]; First Amended Class Action Complaint at 1, Estate of Lokken v. UnitedHealth Grp., 766 F. Supp. 3d 835 (D. Minn. 2025) [hereinafter *Lokken* Complaint]; Class Action Complaint at 1, Est. of Barrows v. Humana, Inc., 2025 WL 2375645 (W.D. Ky. 2025) [hereinafter *Barrows* Complaint].

56. *Lokken* Complaint, *supra* note 55, at 9, 11, 16; *Jong* Complaint, *supra* note 55, at 2; *Barrows* Complaint, *supra* note 55, at 3; *Kisting-Leung* Complaint, *supra* note 55, at 1.

57. *Kisting-Leung* Complaint, *supra* note 55, at 2; *Jong* Complaint, *supra* note 55, at 8-9, 12; *Lokken* Complaint, *supra* note 55, at 40-44, 52, 54; *Barrows* Complaint, *supra* note 55, at 32-39, 44.

intelligence…[to] enhanc[e] patient experience, improv[e] population health, [and] reduc[e] costs."[58]

III. REGULATION AND REMEDIES FOR AI UTILIZATION

Given the "remarkable potential [of AI] to enhance efficiency, expand access, and improve outcomes,"[59] combined with the alarming patient safety risks associated with AI use, the question is how much oversight and protection is necessary to support patient safety, ensure compliant AI utilization with Medicare Advantage rules, and control the risks of AI-related errors? This Comment focuses on the latter option, controlling the risks associated with AI-related harm incurred from automated prior authorization practices. More specifically, this Comment suggests that (1) requiring insurance to cover AI-related injury is an acceptable regulatory mechanism for MACs, and (2) argues CMS has federal authority to mandate insurance as an eligibility requirement and insulate AI utilization within the Medicare Advantage.

A. Regulation of Artificial Intelligence

At the time of this writing, there is no U.S. legislation specifically controlling or regulating the utilization of AI within HHS. Ahead of the United States, the World Health Organization has already issued guiding principles for the use of artificial intelligence.[60] Recognizing that AI governance is necessary, multiple federal and state efforts are underway to gain general control of the ways in which AI is utilized and to gain control of secondary downstream impacts.[61] In 2019, the FDA began exploring a potential regulatory framework for AI-based software utilized as a medical device, and in 2021, published an action plan and guiding principles targeting AI software as a medical device.[62]

---

58. Elliott Crigger et al, *Trustworthy Augmented Intelligence in Health Care*, J. MED. SYS., Jan. 12, 2022, at 1, 1.

59. Khan, *supra* note 35, at 52.

60. *See generally* Tambiana Madiega, *Artificial Intelligence Liability Directive*, EUR. PARLIAMENT (Feb. 2023), https://www.europarl.europa.eu/RegData/etudes/BRIE/2023/739342/EPRS_BRI(2023)739342_EN.pdf (recommending strict liability for high-risk AI systems); *Ethics and Governance of Artificial Intelligence for Health: WHO Guidance*, WORLD HEALTH ORG. xi-xiv (2021), https://iris.who.int/server/api/core/bitstreams/f780d926-4ae3-42ce-a6d6-e898a5562621/content (endorsing six guiding principles for use of AI: (1) protecting human autonomy; (2) promoting human well-being and safety and public interest; (3) ensuring transparency, explainability, and intelligibility; (4) fostering responsibility and accountability; (5) ensuring inclusiveness and equity; and (6) promoting AI that is responsive and sustainable).

61. Airlie Hilliard, *The State of Healthcare AI Regulations in the US*, HOLISTIC AI (Dec. 3, 2024), https://www.holisticai.com/blog/healthcare-laws-us; *See generally State Prior Authorization Bill Tracking 2024*, QUORUM, https://www.quorum.us/spreadsheet/external/IDUVNeFwGGvvDtSqRTod/ (last visited Mar. 10, 2026) (tracking the status of over 200 prior authorization legislative measures that have been introduced and enacted across the country to show widespread efforts to control in prior authorization reviews).

62. *Artificial Intelligence in Software as a Medical Device*, U.S. FOOD & DRUG ADMIN. (Mar. 25, 2025), https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-software-medical-device.

In 2020, the National Association of Insurance Commissioners (NAIC), the insurance industry's leading professional organization, published industry-wide principles for utilization of artificial intelligence.[63] These principles "establish general expectations for AI actors and systems" and include the AI system must be (1) fair and ethical, (2) accountable, (3) compliant, (4) transparent, and (5) secure, safe, and robust.[64]

Notable movement began in 2023. The NAIC published a model bulletin to emphasize that insurers who use artificial intelligence must "comply with all applicable insurance laws and regulations."[65] Then, on behalf of President Biden, the Office of Management and Budget (OMB) requested comments regarding the establishment of a governing AI body, how and what types of coordination efforts would be beneficial, and how executive agencies can improve operational efficiency with AI.[66] OMB then published a memorandum outlining action items related to "Advancing Governance, Innovation, and Risk Management for Agency Use of Artificial Intelligence."[67] President Biden then issued an Executive Order, "Safe, Secure, and Trustworthy Artificial Intelligence" proclaiming foundational AI governance strategies targeting safety, security, privacy, equality, civil rights, consumer protections, and innovation.[68] Several other congressional bills introduced in 2023 underscore the importance of AI governance in order to minimize risks.[69]

Finally, in growing response to concerns about AI-related non-compliance and AI-related discrimination by Medicare Advantage plans, CMS updated their regulations in 2023.[70] CMS mandated that prior authorization can only be used to either confirm a diagnosis for a medical coverage determination or to ensure the

63. NAT'L ASS'N OF INS. COMM'RS, NATIONAL ASSOCIATION OF INSURANCE COMMISSIONERS (NAIC) PRINCIPLES ON ARTIFICIAL INTELLIGENCE (AI) 1-3 (2020), https://content.naic.org/sites/default/files/inline-files/NAIC%20Principles%20on%20AI.pdf.

64. *Id.*

65. NAT'L ASS'N OF INS. COMM'RS, NAIC MODEL BULLETIN: USE OF ARTIFICIAL INTELLIGENCE SYSTEMS BY INSURERS 1 (2023), https://content.naic.org/sites/default/files/inline-files/2023-12-4%20Model%20Bulletin_Adopted_0.pdf.

66. *Request for Comments on Advancing Governance, Innovation, and Risk Management for Agency Use of Artificial Intelligence Draft Memorandum*, 88 Fed. Reg. 75625, 75625-26 (Nov. 3, 2023).

67. Memorandum from Shalanda D. Young, Off. of Mgmt. & Budget Dir., to the Heads of Exec. Dep'ts & Agencies 1 (Mar. 28, 2024), https://www.whitehouse.gov/wp-content/uploads/2024/03/M-24-10-Advancing-Governance-Innovation-and-Risk-Management-for-Agency-Use-of-Artificial-Intelligence.pdf.

68. *FACT SHEET: President Biden Issues Executive Order on Safe, Secure, and Trustworthy Artificial Intelligence,* THE WHITE HOUSE (Oct. 23, 2023), https://bidenwhitehouse.archives.gov/briefing-room/statements-releases/2023/10/30/fact-sheet-president-biden-issues-executive-order-on-safe-secure-and-trustworthy-artificial-intelligence/.

69. Eliminating Bias in Algorithmic Systems Act of 2023, S.3478, 118th Cong. (2023); H.R. Res. 66, 118th Cong. (2023); *see* Improving Seniors' Timely Access to Care, S.4532, 118th Cong. (2024).

70. Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly, 88 Fed. Reg. 22120, 22121-22 (Apr. 12, 2023).

requested service is medically necessary.[71] They determined that all Medicare Advantage plans must observe national and local coverage determinations, and if coverage criteria are not determined, the plan may create internal coverage criteria based on "current evidence in widely used treatment guidelines or clinical literature."[72] This signals that for Medicare Advantage plans using AI, the algorithm cannot use more restrictive coverage guidelines than CMS requires. Finally, CMS directed all MACs to establish a utilization management committee to ensure compliance with the aforementioned rules and coverage requirements.[73] While the updated regulations do not specifically identify that AI applications are prohibited, nor do they target the process by which MACs reach decisions, they do reflect that outcomes of medical coverage determinations must be compliant with federal regulations.[74] Lastly, CMS is implementing new audit procedures to ensure compliance with coverage and benefit conditions and other contract provisions.[75]

Even with emerging federal attention placed on AI, MACs are nonetheless largely governing their own utilization of AI enabled processes. When errors are made during the prior authorization process, financial and bodily harm occur.[76] Many Congressional representatives and healthcare leaders across the nation still call for additional oversight by CMS,[77]

> We believe CMS must be more proactive in monitoring plans' use of AI and algorithm-driven tools. MA plans cannot be allowed to side-step oversight by claiming that these tools are mere "guidance." Given that we do not know what inputs are used for the algorithms and AI tools currently being used, it is difficult to know the accuracy of the information they generate and whether the inputs comply with the regulations.[78]

---

71. *Id.*

72. *Id.* at 22122.

73. *Id.* at 22121-22.

74. *Id.* at 22122.

75. Memorandum from John Scott, Dir. Medicare Parts C & D Oversight & Enf't Grp., to All Current & Prospective Medicare Advantage, Prescription Drug Plan, Section 1876 Cost, & Medicare-Medicaid Plan Orgs. (Dec. 19, 2023) (on file with author), https://www.ahcancal.org/Reimbursement/Medicare/Documents/2024%20Medicare%20Advantage%20Program%20Audits%20Updates%20Memo.pdf; *see also 2023 Part C and Part D Program Audit and Enforcement Report*, CTRS. FOR MEDICARE & MEDICAID SERVS. 3 (July 22, 2024), https://www.cms.gov/files/document/2023-program-audit-enforcement-report.pdf (indicating that audits will be conducted of MACs to ensure compliance with regulations and MACs evaluation may face additional to determine if enforcement action is necessary).

76. Biniek et al., *supra* note 18 ("more than 80% of appeals resulted in partially or fully overturning the initial [medical coverage] decision in 2022…. These requests represent medical care that was…ultimately deemed necessary but was potentially delayed because of the additional step of appealing the initial prior authorization decision.").

77. Letter from Congress to Chiquita Brooks-LaSure, Admin'r of Ctrs. for Medicare & Medicaid Servs. 2 (June 25, 2024) (on file with author), https://chu.house.gov/sites/evo-subsites/chu.house.gov/files/evo-media-document/Final%20Chu-Nadler-Warren%20Letter%20to%20CMS%20to%20Increase%20Oversight%20of%20AI%20in%20Medicare%20Advantage%20Coverage%20Decisions%2006.25.2024.pdf.

78. *Id.*

Given AI is inappropriately denying prior authorizations, beneficiaries are limited to the Medicare appeals process before seeking judicial action to redress any resulting injuries.[79]

B. Remedy for Denied Coverage

A state cause of action for a denied medical coverage determination cannot be brought against a MAC because its preempted by federal Medicare law.[80] "Congress intended for all state laws or regulations that purport[] to regulate [Medicare Advantage] plans offered by MAOs…[to be] preempted."[81] The only option to seek a remedy for a partially or fully denied coverage determination is the federal Medicare Administrative Appeals process.[82]

Reconsideration of a denied medical coverage determination is based on the rationale for the initial denial and any other information that could be of relevance.[83] At all times and levels of review, the reviewing party must issue a determination "as expeditiously as the enrollee's health condition requires."[84] Later stages of review include a hearing in front of an Administrative Law Judge, and if the determination is denied, a review by the Medicare Appeals Council.[85] If the determination is denied again, a review by a Federal District Court is the last option, but typically only if the amount in question is $1,840 or greater[86] and if the Medicare Appeals Council action is final.[87]

Beneficiaries are required to follow and exhaust the administrative appeals process before they pursue federal review against a MAC for denied coverage.[88] This requirement is true even if the beneficiary is seeking damages in addition to approved coverage determination.[89] As the Eleventh Circuit noted, 42 U.S.C. § 405(h) "prevents beneficiaries…from evading administrative review by creatively styling their benefits and eligibility claims as constitutional or statutory challenges to Medicare statutes and regulations."[90] Additionally, the Supreme Court has articulated two methods to decide if a claim falls under Medicare, thus activating

79. *See Managed Care Appeals & Grievances*, CMS.GOV (Nov. 20, 2024), https://www.cms.gov/medicare/appeals-grievances/managed-care.

80. 42 U.S.C. § 1395w-26(b)(3) (2024).

81. Medicaid & Medicare Advantage Prods. Ass'n of P.R., Inc. v. Emanuelli Hernández, 58 F.4th 5, 12 (1st Cir. 2023) (alterations in original).

82. CTRS. FOR MEDICARE & MEDICAID SERVS., PART C & D ENROLLEE GRIEVANCES, ORGANIZATION/COVERAGE DETERMINATIONS, AND APPEALS GUIDE 115 (2024), https://www.cms.gov/medicare/appeals-and-grievances/mmcag/downloads/parts-c-and-d-enrollee-grievances-organization-coverage-determinations-and-appeals-guidance.pdf.

83. 42 C.F.R. § 422.580 (2025).

84. 42 C.F.R. § 422.590(a)(2).

85. CTRS. FOR MEDICARE & MEDICAID SERVS., *supra* note 82, at 115.

86. *Id.*

87. 5 U.S.C. § 704 (2025) (right to appeal final administrative agency action).

88. Escarcega v. Verdugo Vista Operating Co., 2020 WL 1703181, at *7 (C.D. Cal. 2020).

89. *See* Kaiser v. Blue Cross of Cal., 347 F.3d 1107, 1112 (9th Cir. 2003).

90. *See* United States v. Blue Cross & Blue Shield of Al., Inc., 156 F.3d 1098, 1104 (11th Cir. 1998); 42 U.S.C. § 405(h) ("No action…shall be brought…to recover on any claim arising under this subchapter.").

the administrative appeals process.[91] First, if the claims of the beneficiary are "inextricably intertwined" with a claim for benefits, and secondly if the "standing and the substantive basis" for arguing the claim falls under Medicare.[92]

The Ninth Circuit in *Ardary v. Aetna Health Plans*, however, demonstrated that sometimes a claim that derived from a denied coverage determination is nonetheless not required to exhaust the administrative process.[93] There, the plaintiffs pursued a wrongful death action and sought general and punitive damages under state tort law, not recovery of Medicare benefits, even though their claims arose out of a denied benefit determination.[94] Defendant Aetna removed the action to federal court on the grounds that the claims were predicated on the denial of Medicare benefits.[95] They further moved to dismiss because plaintiffs failed to exhaust the administrative appeals process.[96] The Ninth Circuit found the state tort claims were not inextricably intertwined with the denial of benefits and could not be remedied by retroactive authorization because the beneficiary died; thus, plaintiffs were not required to exhaust the administrative appeals process and allowed to bring a state court action.[97]

Therefore, when state actions are not preempted by the federal judicial review requirement[98] because they are "'wholly collateral' to a claim for reimbursement,"[99] or alternatively a party has exhausted the administrative appeals process, a beneficiary can bring a cause of action against MACs. Given that AI-related denials of medical coverage determinations are resulting in harm to beneficiaries, as evidenced by four class-action lawsuits, the question is whether MACs are prepared to face federal and potentially state liability claims for wrongful denials and resulting damages. This Comment identifies that insurance coverage for these MACs is an appropriate regulator for AI-related risk.

---

91. *Kaiser*, 347 F.3d at 1112.

92. Heckler v. Ringer, 466 U.S. 602, 614-15 (1984).

93. Ardary v. Aetna Health Plans of Cal., Inc., 98 F.3d 496, 501 (9th Cir. 1996).

94. *See id.* at 498; Gordy v. CareMore Health Plan, 2019 WL 4390578, at 6* (C.D. Cal. 2019) ("Gordy's claims allege that CareMore is liable because it acted unreasonably in declining to follow CMS standards and the MA Plan in which Gordy was enrolled, leading to the loss of Gordy's leg; thus…Gordy does not seek to regulate his MA Plan in a manner that diverges from the applicable CMS standards and regulations.").

95. *Ardary*, 98 F.3d at 498.

96. *Id.*

97. *Id.* at 500.

98. *See* Escarcega v. Verdugo Vista Operating Co., 2020 WL 1703181 at *11 (C.D. Cal. 2020) ("Two lines of cases have sprung up in relation to the preemption clause. One…holds that the Medicare preemption clause was not intended to reach 'generally applicable state contract and tort law actions'…. In contrast, other cases hold that "some common law claims fall within the ambit of the Act's preemption clause."); Inchauspe v. Scan Health Plan, 2018 WL 566790 at *8 (C.D. Cal. 2018) ("CMS noted that 'other State health and safety standards, or generally applicable standards, that do not involve regulation of an MA plan are not preepmted.").

99. Ancillary Affiliated Health Servs., Inc. v. Shalala, 165 F.3d 1069, 1071 (7th Cir. 1998) (citation modified).

C. Insurance as a Regulatory Mechanism

At the foundation, insurance is a risk management strategy used to pool, reduce, and spread risk, thereby reducing and mitigating against loss.[100] Artificial intelligence is now embedded into daily aspects of our lives, and "nothing requires more risk reduction and management than the emerging technology of AI."[101] As reflected above, AI algorithms have consequences, like all new emerging technologies and processes, and MACs can incur liability. Often though, the liability associated with new tech is unknown in volume or severity.[102] When beneficiaries are harmed because of delayed care from a denied prior authorization, who is responsible—the algorithm creator or the MA plan employing the algorithm?[103] It can be difficult to establish proximate causation and "but for" causation given the unknown risk of harm and the black box effect (lack of human control over the internal functioning of the AI algorithm).[104] "It takes time for any new innovation, such as AI technology, 'to become fully assimilated within everyday tort law.'"[105] The insurance industry is best positioned to handle early claim variations which may be different from later claim types, as a result of improved processes and risk stabilization.[106]

"[I]nsurance law suggests that insurance acts as a substitute for regulation and highlights the ways insurance institutions act as risk regulators."[107] Insurance companies providing AI-related liability coverage can establish industry rules and best safety practices for risk mitigation.[108] It has been proffered that AI-insurance does not require a special insurance policy to curtain liability, but rather, AI-insurance can fit into existing insurance infrastructures with minor adjustments.[109] Like other insurance policies that require compliance to rules and reporting regulations in order to cover liability, AI-insurance would mandate compliance with protocols to ensure that AI-enabled systems operate in a "safe and efficient manner" to reduce risk.[110]

---

100. Lior, *supra* note 53, at 469.

101. *Id.*

102. *Id.* at 479.

103. *See* 42 C.F.R. § 422.212 (2023) ("MA organizations may not contract…to indemnify the organization against any civil liability for damage caused to an enrollee as a result of the MA organization's denial of medically necessary care.").

104. Lior, *supra* note 53, at 480; *see* IRIS DEVRIESE & MIKE CROWL, MUNICH RE MIND THE GAP: A US-FOCUSED ANALYSIS OF AI LIABILITY RISKS AND THE IMPLICATIONS FOR INSURANCE, 13 (2024), https://www.munichre.com/content/dam/munichre/contentlounge/website-pieces/documents/MR_AI-Whitepaper-Mind-the-Gap.pdf/_jcr_content/renditions/original./MR_AI-Whitepaper-Mind-the-Gap.pdf.

105. Lior, *supra* note 53, at 482 (quoting Kyle Graham, *Of Frightened Horses and Autonomous Vehicles: Tort Law and Its Assimilation of Innovations,* 52 SANTA CLARA L. REV. 1241, 1242 (2012)).

106. *Id.* at 484.

107. Shauhin A. Talesh, *Insurance Companies as Corporate Regulators: The Good, the Bad, and the Ugly*, 66 DEPAUL L. REV. 463, 465 (2017).

108. Lior, *supra* note 53, at 486.

109. *Id.* at 471.

110. *Id.* at 472.

The American Hospital Association also recognizes the need for a "non-technical rule[] that address[es] a specific…application" in regard to AI regulation.[111] Given the liability that MA plans are creating by utilizing AI-algorithms, this Comment suggests that CMS should mandate insurance for a specific AI application—any Medicare Advantage plan that utilizes artificial intelligence for a medical coverage determination. A mandatory insurance scheme for MACs will require any private insurance company desiring a MA contract to establish proof of a first party insurance policy if they choose to utilize AI algorithms for medical coverage determinations.[112] This requirement will create a clear path of liability to offset damages caused by AI-algorithms as well as ensure compliance with industry best practices and CMS rules for medical coverage determinations.

IV. CMS AUTHORITY

A. Express Statutory Authority

In 1977, the Health Care Financing Administration (HCFA) was created under the Department of Health and Human Services to administer the Medicare program.[113] HCFA was then renamed the Centers for Medicare and Medicaid in 2001.[114] The Secretary of Health and Human Services has vested authority to promulgate regulations to carry out the administration of Medicare programs, and no other "rule, requirement, or other statement of policy…shall take effect unless" the Secretary propagates it.[115] Specifically, "the Secretary of Health and Human Services…shall make and publish such rules and regulations, not inconsistent with this Act, as may be necessary to the efficient administration" of this Act.[116] Here, the word "shall" is plain, has a straightforward, ordinary meaning and dictates CMS's authoritative scope to promulgate rules and regulations pertaining to administering the Medicare program. "[T]he word 'shall' generally signals a mandatory duty."[117] The HHS Secretary delegates this broad administrative

111. Letter from Lisa Hrobsky, Senior Vice President Legis. & Pol. Affs., Am. Hosp. Ass'n, to Ami Bera, U.S. House of Representatives (May 6, 2024) (on file with author), https://www.aha.org/system/files/media/file/2024/05/aha-response-to-representative-bera-on-artificial-intelligence-in-the-health-care-sector-letter-5-6-2024.pdf.

112. Lior, *supra* note 53, at 524 ("obligating one side of a potentially harmful relationship from which damages may occur to purchase a minimum amount of coverage before [they] can partake in a certain activity.").

113. *Health Care Finance Administration*, FED. REG., https://www.federalregister.gov/agencies/health-care-finance-administration (last visited Mar. 10, 2026).

114. *See* Centers of Medicare & Medicaid Services; Statement of Organization, Functions and Delegations of Authority; Reorganization Order, 66 Fed. Reg. 35437, 35437 (July 5, 2001).

115. 42 U.S.C. § 1395hh(1) (2024).

116. *Id.* § 1302.

117. Bridgeport Hosp. v. Becerra, 108 F.4th 882, 887 (D.C. Cir. 2024) (quoting Kingdomware Techs., Inc. v. United States, 579 U.S. 162, 171-72 (2016)).

authority to establish, develop, implement, and coordinate the standards and guidelines of the Medicare Advantage program to the Administrator of CMS.[118]

Pursuant to this delegation, the CMS Administrator has statutory authority to enter into contracts with those eligible plans to serve as a MAC, when "CMS determines whether the…application meets all the requirements."[119] Eligibility to be a MAC generally includes (1) capacity to support the contract, (2) compliance with conflict-of-interest standards, (3) necessary assets to support the contract, and (4) any "other requirements as the Secretary may impose."[120] Compliance with requirements is determined by the Secretary of HHS, and she has discretion to govern other eligibility requirements.[121]

> After evaluating all relevant information, CMS determines whether the applicant's application meets all the requirements described in this part[,]…if an MA organization fails…to comply with the requirements of the Part C program…under title XVIII of the Act, CMS may deny an application based on the applicant's failure to comply with the requirements of the Part C program.[122]

42 U.S.C. § 1395kk-1 also reflects that the Secretary will determine performance requirements for MACs and will not enter or renew a contract with a MAC if performance requirements are not met.[123] Finally, "[a] contract with any [M]edicare administrative contractor under this section may contain such terms and conditions as the Secretary finds necessary or appropriate."[124] These regulations give broad administrative authority that is both general and specific in nature to HHS and CMS to (1) enact regulations to govern the Medicare program, (2) mandate eligibility requirements to become a MAC, and (3) determine performance requirements for those under contract. As noted in *Northport Health Services of Arkansas., LLC v. United States HHS*, if legislative intent is clear, the agency must act in accordance with that understanding.[125] "[W]hen a statute's language is plain, the sole function of the courts—at least where the disposition required by the text is not absurd—is to enforce it according to its terms."[126] Here, Congressional intent is clear that HHS has the authority to delegate rules and regulations regarding the CMS program and determine eligibility and performance requirements to be an MAC. The assertion of this Comment is that HHS has the

118. Delegation of Authority; Centers for Medicare & Medicaid Services, 76 Fed. Reg. 13618, 13618 (Mar. 14, 2011); Centers of Medicare & Medicaid Services; Statement of Organization, Functions and Delegations of Authority; Reorganization Order, 66 Fed. Reg. at 35437.

119. 42 C.F.R. § 422.502(a)(2) (2024).

120. 42 U.S.C. §§ 1395kk-1(2)(a)-(d).

121. *Id.*

122. 42 C.F.R. §§ 422.502(a)(2)-(b)(1).

123. 42 U.S.C. §§ 1395kk-1(b)(3)-(4).

124. *Id.* § 1395kk-1(c)(1).

125. Northport Health Servs. of Ark., LLC. v. U.S. Dep't of Health & Hum. Servs., 14 F.4th 856, 870 (8th Cir. 2021) (establishing if Congressional intent regarding HHS's authority to regulate arbitration agreements for long term care facilities was clear).

126. Sebelius v. Cloer, 569 U.S. 369, 381 (2013) (quoting Hartford Underwriters Ins. Co. v. Union Planters Bank, N. A., 530 U.S. 1, 6 (2000)).

express authority to make regulations to effectuate the Medicare program, and therefore CMS has the delegated authority to require that MACs carry insurance to cover AI-related damages as a part of the contract eligibility requirements.

B. Statutory Interpretation to Support CMS's Authority

Even if CMS is not considered to have express authority to enact regulations and eligibility requirements for MACs, tools of statutory interpretation support Congress's intention of granting HHS/CMS the authority to determine MAC eligibility requirements. In the absence of express authority, courts do not resolve statutory discrepancies based on equity, justice, or what would be reasonable under the circumstances.[127] The Supreme Court in *Connecticut National Bank v. Germain* explained that interpretive guidelines are tools that assist in uncovering the meaning of legislation when the language is not exact, specific, or could be interpreted in various ways.[128] Statutes must be deciphered to determine the intent and meaning behind the language to resolve the dispute, and the court should not impute or substitute its own judgement.[129] In this case, the Supreme Court found that 28 U.S.C. § 1292 does provide for appellate review of interlocutory orders issued by the district court, even when the district court is sitting as the bankruptcy trial court.[130] In this example, the Court sought "to give effect to the intent of Congress" and avoid enacting its own version of the legislation under the doctrine of separation of powers,[131] which is in alignment with general interpretative guidelines and separation of powers principles. Today, purposivism and textualism are the two leading theories of statutory interpretation that guide statutory understanding.[132]

1. Interpretative Theories

Purposivism argues that "judges should construe statutes to execute [the] legislative purpose" focusing on their intent and the problem they were trying to solve.[133] A prevailing view is "that the legislature is made up of reasonable men pursuing reasonable purposes reasonably," but this interpretation style should not lead to reading into the statute that which is contrary.[134] Under purposivism, judges should be familiar with: how Congress works; how it achieves its purpose, relying on policy context; the informed reasonable person's interpretation; and supportive materials such as the legislative history and other methods on which the legislature

127. VALERIE C. BRANNON, CONG. RSCH. SERV., RL45153, STATUTORY INTERPRETATION: THEORIES, TOOLS, AND TRENDS 4 (2023).

128. Conn. Nat'l Bank v. Germain, 503 U.S. 249, 253 (1992).

129. BRANNON, *supra* note 127, at 4.

130. *Conn. Nat'l Bank*, 503 U.S. at 254.

131. BRANNON, *supra* note 127, at 4 (quoting United States v. Am. Trucking Ass'ns, Inc., 310 U.S. 534, 542 (1940)).

132. *Id.* at 10.

133. *Id.* at 12.

134. *Id.*

relies to reach compromise in getting a bill passed.[135] "Coherence and workability" underly the desire to seek consistency with the legislation's intent and purpose.[136]

Alternatively, the textualist approach "focus[es] on the words of a statute, emphasizing text over any unstated purpose."[137] Textualists concentrate on how the reasonable person would read the text of the statute alongside the rest of the law, evaluate the statutory structure, and ultimately rest their interpretation on the stated language to respect legislative authority without jeopardizing interpretative error.[138] Words of a statute survived the political review process, therefore textualists believe the stated language should be given full authority.[139] Most textualist do not evaluate legislative history as part of statutory interpretation and instead ask "what assumptions [were] shared by the speakers and intended audience" such that they would understand the context and meaning.[140]

2. Interpretative Tools

i. Ordinary Meaning

Often courts utilize aspects of both approaches, purposivism and textualism, in overlapping ways.[141] Often purposivists start with the words of the text (reflective of textualism), and textualists eventually look at the legislature's intent (reflective of purposivism).[142] Overall, courts rely "on five types of interpretive tools: ordinary meaning, statutory context, canons of construction, legislative history, and evidence of the way a statute is implemented," most of which are used together, regardless of if the interpreter is a purposivist or textualist.[143] Ordinary meaning of common words is assumed in statutory interpretation (particularly considering terms of art).[144] 42 U.S.C. § 1302 reflects "the Secretary of Health and Human Services…shall make and publish such rules and regulations…as may be necessary to the efficient administration [of this Act]."[145] "Shall" has a plain and an ordinary meaning. According to the Merriam-Webster Dictionary, "shall" is a verb that is "used in laws, regulations, or directives to express what is mandatory."[146] Therefore, the Secretary has a mandatory obligation to publish rules and regulations which are necessary to administer Medicare Advantage programs. In the emerging age of AI, rules and regulations are necessary to control and guide this use.

---

135. *See id.*
136. *Id.* at 13.
137. *Id.* at 14.
138. *Id.* (citation omitted).
139. *Id.*
140. *Id.* at 15.
141. *Id.* at 17.
142. *Id.*
143. *Id.* at 20-21.
144. *Id.* at 21.
145. 42 U.S.C. § 1302(a) (2024).
146. *Shall*, MERRIAM-WEBSTER DICTIONARY (12th ed. 2025).

ii. Legislative History and Implementation

Legislative history reflects the legislature's deliberations and intentions when enacting a law.[147] History is most commonly used to determine the underlying purpose of the law, but it can also be probative to determine any special meaning to words used.[148] Implementation of a statute is also evaluated to determine how the agency charged with the action interpreted the language in question.[149] While agency interpretation is not dispositive, it is informative of the resolution.[150] As part of the Medicare Modernization Act of 2003, HHS was required to report to Congress on several occasions the implementation plans for awarding Medicare Advantage contracts.[151] The report had to include the number of contracts bid, the transition to the bidding process for Medicare Advantage contracts, and the oversight and management of MACs.[152] This is supportive of Congress's intent that HHS have the authority to manage and have oversight of the Medicare Advantage program.

iii. Statutory Context

Statutory context is taking the few disputed words and comparing and clarifying them against the statute at large or closely related statutes. If the same words or phrases are noted elsewhere in the statutes, courts will try to give the same meaning to the same words or phrases consistently throughout.[153] This is unless the suggested interpretation is more precisely explained elsewhere in the statute; if explained elsewhere, the text in question would not be given the same construction.[154] The Supreme Court declared in *Azar v. Allina Health Services*, "Th[e] Court does not lightly assume that Congress silently attaches different meanings to the same term in the same or related statutes."[155] A noted example is found in *Azar*, where 42 U.S.C. § 1396hh refers to "substantive legal standard," but the Administrative Procedures Act (APA) refers to "substantive rule," and HHS was not interpreting this phrasing the same way.[156] When HHS attempted to attach a different interpretation to the phrase "substantive legal standard" than what had been understood under the APA, impacting the notice-and-comment requirement, the Court determined that HHS's use of the phrasing was inconsistent with

147. BRANNON, *supra* note 127, at 39.
148. *Id.* at 40.
149. *Id.* at 45.
150. *Id.* at 45-46.
151. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 911(g), 117 Stat. 2066, 2386 (2003).
152. *Id.*
153. BRANNON, *supra* note 127, at 25.
154. *Id.* at 26.
155. *See* Azar v. Allina Health Servs., 587 U.S. 566, 574 (2019).
156. *Id.* at 579.

Congressional intent.[157] "[C]ourts aren't free to rewrite clear statutes under the banner of our own policy concerns."[158]

In contrast to *Azar*, the context of 42 U.S.C. § 1395kk-1 does not allow for various interpretations, and the language substantiates the authority granted to CMS by outlining eligibility criteria and functions to be carried out through those Medicare Advantage contracts. "The Secretary may enter into contracts with any eligible entity," and an entity is eligible to enter into a contract only if the entity has the capability to fulfill the contract, complies with conflict of interest standards, has sufficient assets, and meets other requirements the Secretary may impose.[159] "[T]he 'appropriate' Medicare administrative contractor is the Medicare administrative contractor that has a contract under this section with respect to the performance of that function."[160] The language and context of 42 U.S.C. § 1395h confirms Congress's intent for HHS's authority pertaining to MACs.[161] This section details "[t]he administration [of Medicare Part A hospital services] shall be conducted through contracts with Medicare administrative contractors under section 1395kk-1 of this title."[162] The statute goes on to list timely payment requirements and annual HHS reporting requirements for each Medicare Advantage insurer under contract pursuant to § 1395kk-1.[163]

Under 42 C.F.R. § 422.504(a), any entity providing a Medicare Advantage plan is under a contractual obligation to comply with all MA contract provisions, and compliance with provisions are considered "material" to the execution of the program.[164] As an example, MA contractors must "maintain administrative and management capabilities sufficient for the organization to organize, implement, and control the financial, marketing, benefit administration, and quality improvement activities related to the delivery of Part C services."[165] The Medicare Advantage program specifies that all Medicare Advantage organizations "shall assume full financial risk…for the provision of the health care services for which benefits are required to be provided" and that they "may obtain insurance."[166]

If MACs are required to be financially responsible for services to be provided and are permitted to obtain insurance to do so, requiring insurance for AI-damages pertaining to coverage determinations is in alignment with Congress's intent that HHS has authority to determine program requirements. Ultimately, the overall statutory scheme and context concerning MACs and delivery of Medicare Advantage programs supports that Congress fully intended for HHS to determine

157. *Id.*

158. *Id.* at 581.

159. 42 U.S.C. § 1395kk-1(a)(1)-(2) (2024).

160. *Id.* § 1395kk-1(a)(3).

161. *Id.* § 1395h(a).

162. *Id.*

163. *Id.* §§ 1395h(c), (k).

164. 42 C.F.R. § 422.504(a) (2024); *see also* Key Med. Supply, Inc. v. Burwell, 764 F.3d 955, 958 (8th Cir. 2014) ("Congress empowered the Agency to exercise its judgment and discretion in choosing the items that would be subjected to competitive bidding.").

165. 42 C.F.R. § 422.504(a)(16).

166. 42 U.S.C. § 1395w-25(b).

eligibility requirements, the regulations to maintain compliance, and the authority to terminate those not in compliance with the regulations.

iv. Canons of Statutory Construction

Lastly, canons of statutory construction can be used to determine if legislation appropriately supports administrative agency action. "[C]anons supply default assumptions about the way Congress generally expresses meaning."[167] According to the Congressional Research Service, there are fifty-six canons[168] of construction that can be utilized in countless and sometimes conflicting ways.[169] Again in *Connecticut National Bank v. Germain*, the Supreme Court acknowledged that while many scholars debate about statutory interpretation canons, the foremost general canon is the presumption that the "legislature says in a statute what it means and means in a statute what it says."[170] Another prominent canon is the premise that "the specific governs the general."[171] Often this is applied when there is a general provision followed by a specific provision. The specific provision is not meant to consume the general or vice versa.[172] Alternatively, if a specific provision is followed by a general provision, "the general words are usually construed to embrace only objects similar in nature to those objects enumerated by the preceding specific words."[173]

Here, Congress means what it says as evidenced by the statutory language "[t]he Secretary may enter into contracts with any eligible entity to serve as a [M]edicare administrative contractor with respect to the performance of any or all of the functions described."[174] These functions include the capability to be a MAC, sufficient assets to financially support the program, compliance with conflict of interest standards, and "other requirements" deemed necessary.[175] This broad general phrase at the end of a specific list of eligibility requirements indicates that "other requirements" would refer to provisions similar in nature to those previously listed (capacity, compliance, necessary assets), all to be determined by the HHS secretary.[176]

Significantly, the Fifth Circuit in *Texas v. Becerra* confirmed "[s]ilence does not connote ambiguity,"[177] and just because there is no specifically listed requirement for insurance coverage, "sufficient assets to financially support…[program]

167. BRANNON, *supra* note 127, at 27.

168. *Id.* at 51-62.

169. *See id.* at 27-28.

170. Conn. Nat'l Bank v. Germain, 503 U.S. 249, 254 (1992).

171. RadLAX Gateway Hotel, LLC v. Amalgamated Bank, 566 U.S. 639, 645 (2012) (quoting Morales v. Trans World Airlines, Inc., 504 U.S. 374, 384 (1992)).

172. *Id.* at 646.

173. Citizens Ins. Co. of Am. v. Wynndalco Enters. 70 F.4th 987, 999 (7th Cir. 2023) (quoting Yates v. United States, 574 U.S. 528, 545 (2015)).

174. 42 U.S.C. § 1395kk-1(a)(1) (2024).

175. *Id.* § 1395kk-1(a)(2)(A)-(D).

176. *Id.*; *Wynndalco Enters.*, 70 F.4th at 999 (quoting *Yates*, 574 U.S. at 545).

177. Texas v. Becerra, 89 F.4th 529, 542 (5th Cir. 2024).

function[s]"[178] would infer that requiring insurance as an eligibility requirement is permissible. Canons of statutory interpretation are commonly used to evaluate challenges to administrative agency actions, including HHS's authority to enact Medicare rules and regulations.[179] Aside from the express authority granted to HHS, statutory interpretative guidelines support Congress's intention of granting HHS the authority to determine MAC eligibility requirements.

C. Challenges to HHS/CMS's Authority

1. Administrative Procedure Act

It is not uncommon that litigation ensues when HHS implements a substantive regulation requiring an administrative agency to implement a new program or process, often claiming the regulation was promulgated in excess of statutory authority. The APA details the standard of review pertaining to an challenges of agency action.[180] "The reviewing court shall…hold unlawful and set aside [CMS] action, findings, and conclusions found to be arbitrary, capricious, an abuse of discretion…in excess of statutory jurisdiction [or] authority…[and] without observance of procedure required by law."[181] Agency action is not considered arbitrary and capricious unless "the agency entirely failed to consider an important aspect of the problem[,]…an explanation…[is] counter to the evidence[,]…or is so implausible" that the action cannot be just a difference of opinion.[182] Statutory authority, however, was subjected to a controversial review process, and has of late, changed.[183]

2. Chevron *Deference*

Until recently, the Supreme Court, under *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, accorded great deference to HHS/CMS when their authority had been challenged,[184] ultimately disregarding the APA standards.[185] Under *Chevron*, a two-step framework was employed to evaluate if the administrative agency action in question was within the statutory authority of HHS/CMS.[186] First, the court looked to see if Congress's intent about the specific issue under question was clear.[187] If so, the analysis was over; if however,

178. 42 U.S.C. § 1395kk-1(a)(2)(C).
179. 5 U.S.C. § 706 (2024).
180. *Id.*
181. *Id.* §§ 706(2)(A)-(D).
182. Ohio v. Becerra, 87 F.4th 759, 772 (6th Cir. 2023) (quoting Nat'l Ass'n of Home Builders v. Defs. of Wildlife, 551 U.S. 644, 658 (2007) (internal quotation omitted)).
183. Thomas Barnard & McKenna Cloud, *60 Days After Loper: Health Care Impact of Chevron Deference's End*, BAKER DONALDSON (Aug. 28, 2024), https://www.bakerdonelson.com/60-days-after-loper-health-care-impact-of-chevron-deferences-end.
184. Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc., 467 U.S. 837, 844 (1984).
185. Loper Bright Enters. v. Raimondo, 603 U.S. 369, 375 (2024).
186. *Chevron*, 467 U.S. at 842-43.
187. *Id.* at 842.

Congress's intent was not clear, or the language of the legislation was ambiguous, the second question was "whether the agency's answer [was] based on a permissible construction of the statute."[188] Challengers to CMS's authority argued that *Chevron* deference allowed "executive branch agencies essentially to perform legislative functions without being subjected to appropriate judicial review, allow[ed] agencies to impact the rights of parties without following the requirements of traditional rulemaking, and further denie[d] due process to parties."[189]

As an example, in *Nievod v. Sebellius*, the court afforded deference to HHS under *Chevron*. Here, the plaintiff sought a judicial review for denied coverage of a Part D drug that was used for off-label purposes.[190] Not only did the court find no ambiguity in the statutory language (although indicated it was "not a model of clarity"), it stated that even if it had been ambiguous, HHS's denial of drug coverage based on the statutory coverage of Part D drugs was reasonable.[191]

Again, deference to HHS was afforded in *Tennessee Hospital Association v. Azar*, where the hospital association challenged a rule promulgated by HHS that altered reimbursement calculations.[192] The hospital association claimed that the reimbursement rule was not only inconsistent with the Medicaid Act, but also was non-compliant with the public notice requirement of the Administrative Procedure Act.[193] The Sixth Circuit found that HHS reasonably interpreted the Medicaid Act, had a sufficient rationale for the payment rule, but that CMS did not comply with the rulemaking process pursuant to the APA, thus invalidating the rule.[194] Despite being overturned on procedural grounds, this ruling was afforded *Chevron* deference given the rule was a "reasonable interpretation of an ambiguous section of the Medicaid Act."[195]

3. Chevron *Deference Overruled*

In 2023, however, forty years of HHS/CMS deference ended when the U.S. Supreme Court stated that *Loper Bright Enterprises v. Raimondo* overruled *Chevron*.[196] Specifically, the Court stated that, according to the APA, "courts, *not agencies*, will decide 'all relevant questions of law' arising on review of agency action…even those involving ambiguous laws."[197] *Loper* emphasizes that *Chevron* is inconsistent with the APA, because it presumed that ambiguous statutes granted authority to agencies.[198] This occurred under the premise that agencies are experts

188. *Id.* at 842-43.
189. Barnard & Cloud, *supra* note 183.
190. Nievod v. Sebellius, 2013 WL 503089, at *1 (N.D. Cal.2013).
191. *Id.* at *10.
192. Tenn. Hosp. Ass'n v. Azar, 908 F.3d 1029, 1032 (6th Cir. 2018).
193. *Id.* at 1037.
194. *Id.* at 1046-47.
195. *Id.* at 1042.
196. Loper Bright Enters. v. Raimondo, 603 U.S. 369, 412 (2024).
197. *Id.* at 371 (emphasis added) (internal citation omitted).
198. *Id.* at 398.

in their field and thus have the expertise to determine when an ambiguous statute grants them authority.[199] The APA, however, requires courts to "exercise independent judgment when reviewing agency actions."[200] Until *Loper*, HHS was afforded deference for an action that fell under an unclear or ambiguous statutory provision; now, CMS's interpretation of its own statutory authority "may be informative, [but] it 'cannot bind a court.'"[201] The Court's ruling will significantly impact federal health policy[202] and will lead to a more rigorous scrutiny of agency actions by the courts.[203]

There are several projected ways overruling *Chevron* will impact HHS and thus Medicare Advantage going forward.[204] Without *Chevron* deference, the number of disputes regarding medical decision making and the coverage of items or services are likely to increase.[205] Medical coverage determinations often turn on statutory interpretation of the Affordable Care Act, and with no deference afforded to HHS/CMS, beneficiaries will petition the court to consider the language in their favor.[206]

Administration of CMS may also be impacted, as challengers of CMS's authority have a greater chance of being successful against ambiguous statutes.[207] This will force Congress to replace ambiguous statute language with more specific authority than was previously in place, so CMS regulations will be upheld as intended.[208] It is even projected that circuit splits will result as statutory interpretation of ambiguous statutes will vary from jurisdiction to jurisdiction.[209] "Regulations imposing substantive requirements not clearly authorized by statute…may be particularly vulnerable."[210] Ultimately, it is unclear how the judiciary will treat ambiguous statute language and how this ruling will impact new HHS regulation drafting and implementation.[211] What is clear is that *Loper* shifts the balance of power away from executive agencies and back to Congress and the courts.[212]

199. Joshua Weiss et al., *Health Care Impacts Following Chevron Decision*, BROWNSTEIN (July 3, 2024), https://www.bhfs.com/insights/alerts-articles/2024/health-care-impacts-following-chevron-decision.

200. *Id.*

201. Mantha v. QuoteWizard.com, LLC, 347 F.R.D. 376, 394 n.17 (D. Mass. Aug. 16, 2024) (quoting *Loper Bright Enters*., 603 U.S. at 374).

202. Weiss et al., *supra* note 199.

203. Cloud & Barnard, *supra* note 183.

204. *Id.*

205. *Id.*

206. *See id.*

207. *Id.*

208. *Id.*

209. Weiss et al., *supra* note 199.

210. *Id.*

211. *Id.*

212. *See id.*

4. HHS Challenges After Chevron

Post *Chevron*, in July 2024, the state of Oklahoma challenged HHS's authority pertaining to an eligibility requirement for Title X funding in *Oklahoma v. United States HHS.*[213] HHS was expressly authorized by Congress to determine the eligibility requirements for Title X.[214] HHS was further authorized to terminate any grant should the grant recipient fail to meet eligibility requirements.[215] HHS imposed a new eligibility requirement in 2021, after which *Dobbs v. Jackson Women's Health Organization* was decided in 2022.[216] HHS communicated to Oklahoma that *Dobbs* did not interfere with its Title X grant requirements for 2022.[217]

However, due to state law changes regarding to abortion rights, Oklahoma changed their Title X policies.[218] HHS did not support these policy changes because they were not in compliance with grant eligibility requirements.[219] HHS suggested an alternative solution to the policy changes to meet both Oklahoma's and HHS's needs.[220] Initially, Oklahoma agreed to the alternative solution and was awarded a 2023 grant.[221] Nevertheless, Oklahoma eventually decided to stop the alternative solution, in violation of the 2021 rule, and HHS terminated the grant.[222] Oklahoma challenged the termination on several grounds (only one of which is discussed here): Congress's spending power did not allow delegation of eligibility requirements to HHS.[223]

The Tenth Circuit fully endorsed Congressional spending power to "fix the terms on which it shall disburse federal money to the States."[224] This means that Congress has the authority to decide how federal money is distributed. Disbursement of federal funds is dependent on two conditions: the requirements must be unambiguous and "[t]he state must voluntarily and knowingly accept the terms."[225] Oklahoma argued that authority granted to HHS was ambiguous because it was silent regarding the specific 2021 rule.[226] Despite the lack of specificity regarding the 2021 rule in the relevant statutes, Congress specifically granted HHS

213. Oklahoma v. U.S. Dep't of Health & Hum. Servs., 107 F.4th 1209, 1214 (10th Cir. 2024). *See generally Title X Service Grants*, U.S. DEP'T OF HEALTH & HUM. SERVS.: OFF. OF POPULATION AFFS., https://opa.hhs.gov/grant-programs/title-x-service-grants (last visited Mar. 10, 2026). Title X funding pertains to family planning and preventative health services.

214. *See* 42 U.S.C. § 300a-4(a) (2024).

215. *Oklahoma*, 107 F.4th at 1215.

216. *Id.*; Dobbs v. Jackson Women's Health Org., 597 U.S. 215, 300 (2022) (overturning the fundamental right to abortion).

217. *Oklahoma,* 107 F.4th at 1215.

218. *Id.*

219. *Id.*

220. *Id.* at 1215-16.

221. *Id.* at 1216.

222. *Id.*

223. *Id.* at 1214.

224. *Id.* at 1217 (quoting Pennhurst State Sch. & Hosp. v. Halderman, 451 U.S. 1, 17 (1981)).

225. *Id.*

226. *Id.* at 1217-18.

the right to determine eligibility requirements for Title X funding.[227] "Grants and contracts made under this title shall be made in accordance with such regulations as the Secretary may promulgate."[228] The basis for Congress delegating eligibility requirements falls on the understanding that the legislature cannot possibly anticipate every foreseeable program requirement and thus defers this expertise to the agency itself.[229] Congress has frequently used its spending power to expand policy goals by requiring compliance with agency eligibility requirements.[230] Ultimately, all arguments were rejected, and HHS was authorized to terminate Oklahoma's grant based on noncompliance with eligibility requirements.[231]

In August 2024, HHS was challenged again for withholding funding (due to noncompliance) in excess of its statutory authority.[232] In *Tennessee v. Becerra*, HHS withheld Title X grant funding when it found Tennessee did not comply with Title X eligibility requirements after the state banned abortion following *Dobbs*.[233] Tennessee also sought to invalidate HHS's action on the basis that HHS was interfering with Congressional spending power.[234] However, the Sixth Circuit found Congress's delegation to HHS to manage eligibility requirements for Title X funds was explicit.[235] Specifically, the court cited the same provision as found in *Oklahoma v. United States HHS*.[236] The court ultimately found that Title X unambiguously granted HHS authority, recognizing the longstanding practice of Congress to delegate power to make regulations and issue funding based on those regulations to agencies.[237]

V. HHS HAS AUTHORITY TO MANDATE AI-INSURANCE

HHS has express and implied authority to determine eligibility and performance requirements of MACs and terminate those contractors who are found not in compliance. Given the unknown legal landscape of AI-related damages and the lack of state and federal regulations surrounding the constantly emerging technology, MACs may already be making the decision to carry AI-insurance as a necessary way to insulate itself from AI-risk. CMS requires MACs to maintain capabilities to ensure delivery of MA plans; by requiring AI-insurance as an eligibility criterion, CMS is ensuring all Medicare Advantage plans optimize those capabilities through risk mitigation and financing loss. CMS can create rules and regulations to determine eligibility criteria to become a MAC and has the necessary

227. *Id.* at 1218.
228. 42 U.S.C. § 300a-4(a) (2024).
229. *Oklahoma*, 107 F.4th at 1218 (citing South Dakota v. Dole, 483 U.S. 203, 206 (1987)).
230. *Id.* at 1219 (quoting Fulliove v. Klutznick, 448 U.S. 448, 474 (1980)).
231. *Id.* at 1214.
232. Tennessee v. Becerra, 117 F.4th 348, 355 (6th Cir. 2024).
233. *Id.* at 356-57.
234. *Id.* at 358.
235. *Id.* at 358-59.
236. *Id.* ("Grants…made under this subchapter shall be made in accordance with such regulations as the Secretary may promulgate" and "shall be payable…subject to such conditions as the Secretary may determine to be appropriate.") (quoting 42 U.S.C. § 300a-4(a)-(b) (2024)).
237. *Id*. at 359-60.

authority to require insurance as eligibility criteria to help regulate benefit administration, promote quality improvement activities, and reduce liability. When CMS requires AI-insurance as eligibility criteria, it is exercising its authority to ensure that MACs are compliant with its standards.[238]

Case law post-*Chevron* further supports CMS's interpretation of the Social Security Act as granting authority to promulgate necessary regulations such as AI-insurance, and this would be viewed as neither arbitrary nor capricious. Challengers to CMS requiring AI-insurance are likely to argue CMS is exceeding the scope of its authority if it required AI-insurance. However, the courts have explicitly held that HHS has clearly delegated authority to CMS to determine eligibility requirements for federal funding, as was found in *Oklahoma v. United States HHS* and *Tennessee v. Becerra*, and the statutory language granting HHS authority in both scenarios is fairly similar.[239]

As found in *Oklahoma* and *Tennessee*, "[g]rants and contracts made under this [title] shall be made in accordance with such regulations as the Secretary may promulgate[]" affords HHS authority to determine who gets a contract.[240] Here, very similar statutory language is noted, "the Secretary of Health and Human Services…shall make and publish such rules and regulations, not inconsistent with this [Act], as may be necessary to the efficient administration" of this Act.[241] HHS is granted authority to determine who meets eligibility requirements, to determine who maintains performance requirements, and to terminate the contract if non-compliance is not remedied. Regardless of express authority, interpreted authority, or case law precedent, HHS has the authority to require AI-insurance of MACs to effectuate and promulgate the lawful and safe delivery of Medicare Advantage plans.

CONCLUSION

CMS manages the Medicare Advantage program on behalf of HHS. A major provision of Medicare Advantage plans includes the requirement that beneficiaries obtain prior authorization that the plan will pay for a specific service or treatment. Several major MACs are now employing AI-tools to complete the prior authorization review. These automated AI reviews are resulting in inappropriate denials and wrongful delays in approving necessary medical care for beneficiaries, resulting in monetary loss and physical injury. With the emergence of AI, both the healthcare and insurance industries, in addition to state and federal governments, are recognizing the need for AI-regulation. Insurance has been established as an effective regulatory mechanism for new technology and is applicable to emerging

238. § 1395kk-1(2).

239. *Becerra*, 117 F.4th at 358-59. ("Grants…shall be made in accordance with such regulations as the Secretary may promulgate and shall be payable…subject to such conditions as the Secretary may determine to be appropriate.") (quoting § 300a-4(a)-(b)); § 1302(a) ("the Secretary of Health and Human Services, respectively, shall make and publish such rules and regulations, not inconsistent with this [Act], as may be necessary to the efficient administration of the functions with which each is charged under this [Act].").

240. § 300a-4(a).

241. § 1302(a).

AI technologies. CMS not only has express authority in the Medicare Act, but also implied authority and case law precedent, to support a mandate that any MAC, as part of their contractual requirement, must maintain AI-insurance for liability coverage where an AI-enabled process is utilized for coverage determinations.