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Provider Reimbursement Disputes Go Back to 1984 Following Supreme Court's Regulatory Reset

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One could forgive the healthcare industry for thinking someone drove Doc Brown's DeLorean time machine through One First Street when it awoke on Friday, June 28, to a blast from the past.

No, Ronald Reagan is not the President; Bruce Springsteen's *Born in the U.S.A.* album is not this summer's biggest musical hit; and we have all known for quite some time who we are going to call when a poltergeist marauds through town. But on June 28, 2024, the United States Supreme Court sent the healthcare industry and its chief regulator, the Department of Health and Human Services ("HHS") and its Centers for Medicare and Medicaid Services ("CMS"), back to 1984 when it issued its decision in *Loper Bright Enters. v. Raimondo* and *Relentless, Inc. v. Department of Commerce*[1]and overruled *Chevron U.S.A. Inc. v. Nat. Res. Def. Council, Inc.*,[2] Inc. in a 6–3 decision that effectively turned back the clock 40 years to when the landmark agency deference case was first decided.

The Supreme Court's decision makes one thing clear – that courts, not agencies, have the ultimate authority to interpret Congressional statutes. The new *Loper Bright* framework poses many questions to the reimbursement landscape and is likely to result in increased provider challenges to agency action and more success for providers in those challenges.

Understanding the Past: The Old Framework for Agency Deference Under *Chevron*

Prior to the Supreme Court's *Loper Bright* decision, the *Chevron* doctrine for agency deference devised a two-step framework for courts to use to interpret statutes administered by Federal agencies and determine whether an agency's action based on its interpretation of a statute – i.e., its creation and implementation of rule or regulation – was permissible such that the courts should defer to the agency's interpretation rather than institute their own independent judgment.[3]

The first step in this framework was to discern Congressional intent – whether Congress had directly spoken to the precise question at issue.[4] Under *Chevron*, if the intent of Congress was clear, no further inquiry was needed, and courts were directed to reject agency actions that were contrary to clear congressional intent and apply the statute as it was written.[5] Where a statute was silent or ambiguous with respect to the specific issue at hand, however, courts were required to set aside their own interpretations of the statute, and instead, defer to the agency's interpretation so long as the interpretation was a permissible construction of the statute, even if the court would have reached a different conclusion than the agency.[6]

In practice, *Chevron* applied "when it appears that Congress delegated authority to the agency generally to make rules carrying the force of law and that the agency interpretation claiming deference was promulgated in the exercise of that authority."[7] This threshold requirement was sometimes called *Chevron*'s "step zero" and largely limited *Chevron* to matters involving notice-and-comment rulemaking, which is the most prominent process that agencies must follow to formulate, amend, or repeal a rule under the Administrative Procedure Act ("APA").[8]

Chevron's deference was not warranted where an agency failed to follow notice-and-comment rulemaking in issuing a regulation.[9] For example, under *Chevron*, a court would not have been required to defer to the CMS Medicare coverage requirements if such requirements were issued pursuant to a Local Coverage Determination ("LCD"), as LCDs are promulgated through informal processes rather than formal notice-and-comment rulemaking as required under the APA.

While nothing in *Chevron* prevented providers from challenging agency actions and asking courts to nullify unreasonable agency constructions of statutes under the APA's scope of review provision,[10] such challenges were difficult to win given the expansive agency deference by courts, which consequently made it exceedingly difficult for a plaintiff to demonstrate that an agency's action was unlawful under the APA.[11]

The New (Old) Framework Under *Loper Bright: Look to the APA*

In overturning *Chevron*, the Supreme Court found that *Chevron* was fundamentally incompatible with the APA because the APA delineates that the courts, not the agencies, are tasked with deciding questions of law by applying their own judgment rather than an agency's judgment.[12] Specifically, the APA directs that "[t]o the extent necessary to decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action."[13] Moreover, the Court held that *Chevron*'s key assumption – that statutory ambiguities are implicit delegations to agencies – cannot be reconciled with the APA, particularly because agencies have no special competence in resolving statutory ambiguities, while courts do have such special competence.[14]

With *Chevron* dismantled, courts are required to institute their own independent judgment to determine the best meaning of a statute.[15] Such is the case even where the statute's meaning is that the agency is authorized to exercise a degree of discretion, give meaning to a statutory term, provide the details of a statutory scheme, or regulate subject to the limits imposed by a term or phrase (e.g., "appropriate" or "reasonable") that leaves agencies with flexibility.[16] Thus, "[w]hen the best reading of a statute is that it delegates discretionary authority to an agency, the role of the reviewing court under the APA is, as always, to independently interpret the statute and effectuate the will of Congress subject to constitutional limits."[17]

Significantly, that does not mean that courts should ignore agencies when interpreting statutes. While

courts are no longer bound by agencies' interpretations, an agency may nevertheless help inform and persuade a court to concur with its interpretation to the extent it rests on factual premises within the agency's expertise.[18] Indeed, the Court notes that "[s]uch expertise has always been one of the factors which may give an Executive Branch interpretation particular 'power to persuade if lacking the power to control.'"[19]

How Can Providers Use this Change for Medicare Reimbursement and Appeals?

Many Medicare overpayment determinations and refunds, including those warranted by provider self-audits, and appeals of the same are determined to some degree by CMS' statutory interpretations and resultant rulemaking and guidance. Now, those determinations may be subject to heightened scrutiny under *Loper Bright*. While the relevance and application of *Loper Bright* formany of these determinations will be fact-dependent, below are some provider considerations in key reimbursement areas given the new regulatory framework.

1. ***Contractor overpayment demands***. While Medicare contractors will continue to have authority to audit providers and subject them to overpayment demands and recoupments under the various statutes such as the Medicare Integrity Program,[20]there may exist new opportunities for providers to limit the Medicare contractors' ability to use and rely upon, for example, statistical extrapolations to recover substantial amounts of alleged overpayments from providers. As many providers are aware, CMS and the Office of Inspector General – Office of Audit Services ("OIG-OAS") are very fond of using purported statistically valid random sampling ("SVRS") of a subset of claims to determine that a provider was significantly overpaid, often resulting in alleged overpayment of hundreds of thousands, if not millions, of dollars. For some providers, these types of overpayments spell a death knell on their business.

While CMS and OIG have developed many rules and published much guidance discussing how contractors and other reviewing agencies should utilize and perform extrapolations, the Medicare Integrity Program statute is surprisingly sparse on the topic and merely states that "A medicare contractor may not use extrapolation to determine overpayment amounts to be recovered by recoupment, offset, or otherwise unless the Secretary determines that (A) there is a sustained or high level of payment error; or (B) documented educational intervention has failed to correct the payment error."[21] What constitutes a "sustained or high level of payment error" is not clearly defined, nor what constitutes "educational intervention."

It is certainly foreseeable that providers will seek to challenge the government's current use of extrapolation, including the methodologies that contractors are directed to implement under the Medicare Program Integrity Manual and other Medicare guidance, using their own third-party statisticians to argue that such extrapolation, as currently implemented, overinflates a provider's payment error, is unreliable or statistically invalid, or is otherwise problematic, which may lead to the courts developing their own criteria for when extrapolation may be used and how it should be used.

2. ***Settlement potential.***Medicare contractors may now be more willing to utilize the settlement authority conferred upon them by federal law to resolve overpayment demands rather than risk losing during the appeal process. Although many providers have found CMS to be unwilling to negotiate settlements of overpayment demands or have found CMS' settlement conference facilitation initiative to be an unhelpful alternative dispute resolution process after appealing an overpayment demand, federal law clearly confers upon the HHS Secretary the authority to implement a consent settlement with an affected provider, which is "an

agreement between the Secretary and a provider of services or supplier whereby both parties agree to settle a projected overpayment based on less than a statistically valid sample of claims and the provider of services or supplier agrees not to appeal the claims involved."[22]While such settlements may only be used when the overpayment is not based on a statistically valid sample, to the extent that providers are successful in restricting CMS' ability to utilize extrapolated overpayments, the government may become more willing to offer such settlements. Of course, if providers overall experience increased success in appealing overpayment demands under *Loper Bright*, then their incentive to settle overpayment cases – even those involving substantial sums of money – is significantly lower.

3. ***Self-audits and potential refunds.***CMS has many requirements for providers to review and refund potential overpayments, including the timeliness of identifying and returning such overpayments and what constitutes an overpayment, which may now be subject to heightened scrutiny. For example, one key CMS rule that providers may target under*Loper Bright* is the "Medicare Program; Reporting and Returning of Overpayments" final rule published on February 12, 2016.[23] The rule requires providers and suppliers receiving funds under the Medicare program Parts A and B to report and return overpayments by the later of the date that is 60 days after the date on which the overpayment was identified, or the date any corresponding cost report is due, if applicable, and clarifies that "a person has identified an overpayment when the person has or should have, through the exercise of reasonable diligence [which CMS defines as "at most 6 months from the receipt of credible information"], determined that the person has received an overpayment and quantified the amount of the overpayment" based on "credible information about a potential overpayment."[24] CMS states that credible information "includes information that supports a reasonable belief that an overpayment may have been received" and "[d]etermining whether the information is sufficiently credible to merit an investigation is a fact-specific determination."[25]

The final rule derives from Section 1128J(d) of the Social Security Act, which merely requires a person to report and return an identified overpayment "60 days after the date on which the overpayment was identified" or on "the date any corresponding cost report is due, if applicable."[26] Notably, the statute upon which CMS' final rule is based is silent as to the circumstances under which an overpayment becomes identified, while CMS purports to supplement the statute with its own interpretations for what the identification of an overpayment entails—i.e., through reasonable diligence that should last no longer than six months based on credible information about a potential overpayment, which in and of itself is a fact-dependent exercise and may not always be warranted.

Under *Chevron*, CMS' 60-day overpayment rule requirements were afforded complete deference by the courts, and providers were left to fend for themselves to determine whether something constituted credible information of an overpayment that warranted an investigation. Now, however, under *Loper Bright*, providers have more leeway to challenge the reasonableness of CMS' independent requirements that are not found under the statute.

Notwithstanding, this is an area where providers may want to argue for and against the 60-day rule depending upon the situation or the given provider's preferences and risk tolerance. Indeed, many providers currently have established policies and practices in place to adhere to the 60-day rule and know exactly when and under what circumstances any overpaid claims need to be extrapolated and/or refunded. Now, however, courts may be free to make up their own interpretation of what constitutes an identifiable overpayment, which may leave providers with far less time to research and identify potential overpayments. For example, courts may find that an overpayment is "identified" (as that term is used in the statute) much earlier in the process, leading providers to have to conduct

internal audits and, if necessary, statistical extrapolations in a very short period of time. Moreover, different courts could have separate interpretations on this question, which would leave providers with different rules to follow depending on the jurisdiction, and which can cause significant hurdles for providers (particularly larger providers) who wish to have uniform policies and procedures regardless of where they practice.

Thus, providers should not ignore the current rules in place governing self-audits and overpayment returns out of an abundance of caution. Nevertheless, there exists the potential to challenge CMS' final rule and argue that CMS' final rule is unreasonable and ambiguous, and more clarity is needed to determine what credible information warranting an investigation really means and when an overpayment is truly identified – clarity that should now come from the courts rather than solely from the agency according to the Supreme Court.

4. ***Overpayment appeals.*** This area is perhaps the one with the most opportunity for providers to see increased success given CMS' heavy reliance upon regulations and sub-regulatory guidance to impose overpayment demands upon providers. On the other hand, at least as it pertains to overpayment demands founded upon alleged noncompliance with sub-regulatory guidance such as LCDs and Medicare manuals, it is possible that not much changes given that such sub-regulatory guidance does not undergo the formal rulemaking process pursuant to the APA, and therefore, courts were not required to defer to CMS in such instances. For providers who wish to challenge both an overpayment demand via the regulatory Medicare appeals process as well as the rule(s) upon which CMS bases the overpayment demand in federal court under the APA, these actions will need to be maintained concurrently.

At the very least, *Loper Bright* provides a stronger basis for providers to push back on these overpayments through the Medicare overpayment appeal process, Administrative Law Judges ("ALJs"), the Medicare Appeals Council, and the applicable district courts reviewing such agency actions and appeals should be even less inclined to defer to CMS' overpayment determinations when they are founded on alleged noncompliance with sub-regulatory guidance standing alone. Often, providers have colorable arguments that they have complied with the medical necessity requirements for the services at issue under the applicable statute(s) notwithstanding compliance with sub-regulatory guidance expanding upon the same, and in these instances, providers may expect greater success on appeal.

Lastly, providers who are actively engaged in overpayment appeals may wish to use *Loper Bright* as a means of overturning the initial adverse determination or subsequent unfavorable appeal decisions to the extent that the rule(s) that CMS or its contractors relied on in making the initial overpayment determination is later overturned or deemed invalid by a federal court by the time the appeal is brought before the ALJ, Medicare Appeals Council, or federal district court. However, prior final appeal decisions that were adjudicated before *Loper Bright* was decided and that have exhausted their appeal options are unlikely to be retroactively affected as a result of the Court's ruling, as the Supreme Court explicitly states that its ruling does "not call into question prior cases that relied on the *Chevron* framework. The holdings of those cases that specific agency actions are lawful. . . .are still subject to statutory stare decisis despite our change in interpretive methodology."[27]

These scenarios are just a few examples of the reimbursement-related issues that providers will want to consider moving forward, and which may eventually be litigated based on *Loper Bright*. While it remains to be seen to what extent *Loper Bright* ultimately affects provider reimbursement day-to-day and long-term, providers should be sure to consult with their outside legal counsel to address past, present, and potential reimbursement issues to determine how *Loper Bright* presents them with new

opportunities and tools to challenge contractor overpayments, conduct self-audits, determine whether voluntary overpayment refunds are warranted, and more – including challenging CMS' regulations under the APA.[28]

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[1] No. 22-451 and No. 22-1219, 2024 WL 3208360 (U.S. June 28, 2024). These two cases were decided in the same opinion.

[2] 467 U.S. 837 (1984).

[3] *See Loper Bright*, 2024 WL 3208360, at *6, 14.

[4] *Id.* at *14.

[5] *Id.*

[6] *Id.*

[7] *Id.* at *18 (citing *U.S. v. Mead Corp.*, 533 U.S. 218, 266-227 (2001)).

[8] *Loper Bright*, 2024 WL 3208360, at *18.

[9] *Loper Bright*, 2024 WL 3208360, at *18 (citing *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 220 (2016)); 5 U.S.C. § 553.

[10] *See* 5 U.S.C. § 706.

[11] Specifically, the APA directs courts to hold unlawful and set aside any agency action, findings, and conclusions that are found to be (A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law; (B) contrary to constitutional right, power, privilege, or immunity; (C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right; (D) without observance of procedure required by law; (E) unsupported by substantial evidence in a case subject to sections 556 and 557 of this title or otherwise reviewed on the record of an agency hearing provided by statute; or (F) unwarranted by the facts to the extent that the facts are subject to trial de novo by the reviewing court. *Id.*

[12] *Loper Bright*, 2024 WL 3208360, at *12; 5 U.S.C. § 706 (specifying that courts will decide "all relevant questions of law" arising on review of agency action).

[13] 5 U.S.C. § 706

[14] *Loper Bright*, 2024 WL 3208360, at *16.

[15] *Id.* at *13.

[16] *Id.* (citing *Batterton v. Francis*, 432 U.S. 416, 425 (1977); *Wayman v. Southard*, 10 Wheat. 1, 43, (1825); *Michigan v. EPA*, 576 U.S. 743, 752 (2015)).

[17] *Loper Bright*, 2024 WL 3208360, at *14.

[18] *Id.* at *17.

[19] *Id.* (citing *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944)).

[20] *See* 42 U.S.C. § 1395ddd.

[21] *Id.* at (f)(3).

[22] *Id.* at (f)(5).

[23] 81 Fed. Reg. 7654 (Feb. 12, 2016) (codified at 42 C.F.R. pts. 401, 405).

[24] *Id.* at 7654, 7661-7662.

[25] *Id.* at 7662.

[26] 42 U.S.C. § 1320a-7k(d)(1)-(2).

[27] *Loper Bright*, 2024 WL 3208360, at *21.

[28] Significantly, the Supreme Court in *Corner Post, Inc. v. Board of Governors of the Federal Reserve Sys.*, No. 22-1008, 2024 WL 3237691 (Jul. 1, 2024) held that the limitations period to file an APA challenge under 28 USC 2401(a) (the default six-year statute of limitations period for suits against the United States) begins to run when the *specific plaintiff* in the suit is injured by the final agency action, as opposed to when the agency action occurred. Thus, under *Corner Post*, every new commercial entity may bring a new APA challenge, even for agency actions (like the issuance of regulations) that occurred years prior provided that the APA suit is filed within 6 years from the date of the entity's formation. Such a decision further opens up agency rulemaking – even rulemaking spanning decades past – to a potentially high volume of federal court challenges.

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