ADVISORY OPINION 24-02 ON THE SCOPE OF STATES' AUTHORITY TO EXCLUDE PROVIDERS FROM PARTICIPATION UNDER A MEDICAID STATE PLAN

December 11, 2024

This Advisory Opinion addresses a State's authority to exclude a provider from participation under a State plan under Title XIX of the Social Security Act ("the Act"). In particular, it addresses whether a State may exclude a provider on the ground that the provider has purportedly violated federal law by mailing or otherwise delivering the prescription drugs mifepristone or misoprostol to any person, in cases where the provider has acted in reliance on a recent opinion of the Department of Justice's Office of Legal Counsel that determined the relevant conduct not to be in violation of federal law. The answer is no. The Act permits a State to exclude a provider from participation under its State plan in cases where the provider is not capable of performing the required medical services in a professionally competent manner, or in certain cases where a provider has been convicted of a criminal offense or has committed certain forms of professional malfeasance. These grounds for exclusion are not implicated, however, where a provider mails or otherwise delivers these drugs under the circumstances described in OLC's opinion, and in reliance on that opinion.

I. BACKGROUND

A. *The Medicaid Statute*

Although participation in the Medicaid program is voluntary, a State that chooses to do so must comply with certain requirements established under title XIX of the Act and the Secretary's implementing regulations. Under Section 1902(a)(23) of the Act, a State plan for medical assistance must:

> provide that (A) any individual eligible for medical assistance … may obtain such assistance from any … person … qualified to perform the service or services required … who undertakes to provide him such services, and (B) an enrollment of an individual eligible for medical assistance in a primary care case-management system (described in section 1396n(b)(1) of this title), a medicaid managed care organization, or a similar entity shall not restrict the choice of the qualified person from whom the individual may receive services under section 1396d(a)(4)(C) of this title, …, except that nothing in this paragraph shall be construed as requiring a State to provide medical assistance for such services furnished by a person or entity convicted of a felony under Federal or State law for an offense which the State agency determines is inconsistent with the best interests of beneficiaries under the State plan ….

42 U.S.C. § 1396a(a)(23). This provision, known as the "free choice of provider" provision, limits a State's authority to restrict a Medicaid beneficiary's access to a provider, if that provider

is willing and qualified to provide a covered medical service to that beneficiary.[1] In addition, the State plan must include—and receive approval from the Secretary for—its description of "the standards, for private or public institutions in which recipients of medical assistance under the plan may receive care or services, that will be utilized by the State authority or authorities responsible for establishing and maintaining such standards[.]" 42 U.S.C. § 1396a(a)(22). Under 42 C.F.R. § 431.51(c)(2), a State may "set[] reasonable standards relating to the qualifications of providers."

In addition to its authority to set qualification standards for providers, a State may also exclude a provider from participation under its plan as a sanction for certain forms of misconduct specified in the Medicaid statute. Section 1902(p)(1) provides that:

> In addition to any other authority, a State may exclude any individual or entity for purposes of participating under the State plan under this title for any reason for which the Secretary could exclude the individual or entity from participation in a program under title XVIII under section 1128, 1128A, or 1866(b)(2).

42 U.S.C. § 1396a(p)(1). The cross-referenced sections describe certain circumstances under which the Secretary may (or, in some cases, must) exclude a provider from participation in the Medicare program as a result of the provider's criminal conviction or similar malfeasance. See *id.* (cross-referencing 42 U.S.C. §§ 1320a-7, 1320-a7a, and 1395cc(b)(2)).[2] The Secretary is

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[1] Although States may implement a Medicaid managed care organization model that restricts a beneficiary's access to a provider in certain circumstances, the statute clarifies that the enrollment of an individual in coverage under such a model shall not restrict the indvidual's choice of the qualified person from whom the individual may receive family planning services that are covered under Section 1905(a)(4)(C) of the Act, 42 U.S.C. § 1396d(a)(4)(C). See also 42 C.F.R. § 431.55(b)(2)(iv).

[2] Section 1128(a) of the Act requires the Secretary to exclude an individual or entity from participation in the Medicaid program if it has been convicted of "a criminal offense related to the delivery of an item or service under title XVIII or under any State health care program," "a criminal offense relating to neglect or abuse of patients in connection with the delivery of a health care item or service," "a criminal offense consisting of a felony relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct" in connection with the delivery of a health care item or service, or "a felony relating to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance." 42 U.S.C. § 1320a-7(a). In addition, Section 1128(b) of the Act permits the Secretary to exclude an individual or entity if it has been convicted of certain other felonies or misdemeanors; if a State licensing authority has suspended or revoked its license, or if it has been suspended or excluded from participation in any federal or state health care program "for reasons bearing on the individual's or entity's professional competence, professional performance, or financial integrity"; if it has furnished services to patients of a quality which fails to meet professional standards of care; if it has committed fraud or has made false statements in connection with a claim for payment; or if it has failed to cooperate with an investigation by the Secretary or has failed to comply with a request for corrective action. 42 U.S.C. § 1320a-7(b). Section 1128A of the Act imposes civil monetary penalties on providers who present false claims for payment to

authorized to require a State to develop a mechanism to implement its exclusion authority under Section 1902(p)(1). See 42 U.S.C. § 1396a(a)(4), (39).

B. *The Comstock Act*

The Comstock Act has a "long and complex history." Appl. of the Comstock Act to the Mailing of Prescr. Drugs That Can Be Used for Abortions, 46 Op. O.L.C. ___, slip op. at 3 (Dec. 23, 2022) ("OLC Opinion"). Originally enacted in 1873, the Comstock Act was primarily used to prosecute the distribution of purportedly obscene matter through the mails. The Act originally included several restrictions against the conveyance of things designed to prevent conception or to produce abortion. See *id.*

In its current form, the Comstock Act declares in relevant part that "[e]very article or thing designed, adapted, or intended for producing abortion," as well as "[e]very article, instrument, substance, drug, medicine, or thing which is advertised or described in a manner calculated to lead another to use or apply it for producing abortion," to be "nonmailable matter." 18 U.S.C. § 1461. The statute further makes it a felony to "knowingly use[] the mails for the mailing, carriage in the mails, or delivery" of any such things, or to "knowingly cause[]" them "to be delivered by mail according to the direction thereon." *Id.* In addition, 18 U.S.C. § 1462 makes it unlawful to bring those same things "into the United States, or any place subject to the jurisdiction thereof," and it prohibits the knowing use of "any express company or other common carrier or interactive computer service" for "carriage" of such items "in interstate or foreign commerce."

The Office of Legal Counsel of the U.S. Department of Justice ("OLC") has concluded that the Comstock Act "does not prohibit the mailing of certain drugs that can be used to perform abortions where the sender lacks the intent that the recipient of the drugs will use them unlawfully." OLC Opinion at 1. In reaching that conclusion, OLC relied on the settled understanding of the Judiciary, Congress, and the Executive Branch over the past century that the statute does not prohibit a sender from conveying such items unless the sender intends that they be used unlawfully. *Id.* at 3. See also *id.* at 3-11 (discussing, *e.g.*, *United States v. Nicholas*, 97 F.2d 510 (2d Cir. 1938), and *Consumers Union of United States, Inc. v. Walker*, 145 F.2d 33 (D.C. Cir. 1944)). The U.S. Postal Service has accepted this limiting construction of the statute in administrative rulings, and has informed Congress that it has done so. *Id.* at 11. Congress was aware of this construction when it amended related portions of the Comstock Act. *Id.* Accordingly, OLC reasoned, Congress ratified this settled understanding of the scope of the statute. *Id.* at 11-15.

OLC further noted that "[f]ederal law does not prohibit the use of mifepristone and misoprostol for producing abortions," and that "the FDA has determined the use of mifepristone in a regimen with misoprostol to be safe and effective for the medical termination of early pregnancy." *Id.* at 17. "[T]hese drugs can serve important medical purposes and

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the Secretary, and permits the Secretary to exclude such providers from participation in the Medicare program. 42 U.S.C. § 1320a-7a. Section 1866(b)(2) of the Act permits the Secretary to refuse to enter into, or renew, a participation agreement with a provider under similar circumstances as those described in Sections 1128 and 1128A. 42 U.S.C. § 1395cc(b)(2).

recipients in every state can use them lawfully in some circumstances." *Id.* "This is true even when the drugs would be delivered to an address in a jurisdiction with restrictive abortion laws, because women who receive the drugs in all fifty states may, at least in some circumstances, lawfully use mifepristone and misoprostol to induce an abortion." *Id.* Thus, OLC concluded, "in light of the many lawful uses of mifepristone and misoprostol," it may not be presumed that a person that delivers these drugs through the mails or through another common carrier does so with an unlawful intent. *Id.* at 20-21 (citing *Youngs Rubber Corp. v. C.I. Lee & Co.*, 45 F.2d 103, 110 (2d Cir. 1930)).

OLC's published formal written opinion is binding within the Executive Branch. See *Citizens for Resp. & Ethics in Washington v. United States Dep't of Just.*, 922 F.3d 480, 484 (D.C. Cir. 2019).

II. ANALYSIS

The free choice of provider provision in Section 1902(a)(23), read together with Section 1902(p)(1), constrains a State's authority to exclude providers from the Medicaid program for reasons unrelated to the provider's competence to provide medical services. Section 1902(a)(23) does not permit a State to set provider "qualifications" in a vacuum; instead, the statute specifies that the relevant inquiry is whether a provider is "*qualified to perform* the service or services required." 42 U.S.C. § 1396a(a)(23) (emphasis added). A contrary reading would render the "free choice of provider" provision to be a nullity, as a State would be free to negate the beneficiary's choice of provider by setting qualification standards unrelated to the provider's ability to perform the required service. Accordingly, the Centers for Medicare & Medicaid Services ("CMS") has historically understood that a qualification standard is permissible under Section 1902(a)(23) only if it relates to the provider's capability "to perform the required services in a professionally competent, safe, legal, and ethical manner" or to "the ability of the provider to appropriately bill for those services." Ctr. for Medicaid and CHIP Servs., CMS, State Medicaid Director Letter 16-005 at 2 (Apr. 19, 2016). See also Decision of the Admin'r at 31, *In re Disapproval of Indiana State Amendment SPA 11-011* (CMS May 30, 2013).[3] The agency's reading of Section 1902(a)(23) is in accordance with the weight of authority in the federal courts of appeals.[4]

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[3] A subsequent Administration rescinded State Medicaid Director Letter 16-005 in 2018, but did not offer a contrary interpretation of Section 1902(a)(23). See State Medicaid Director Letter 18-003 (Jan. 19, 2018). The 2018 letter, however, did not engage with the 2016 letter's reasoning or acknowledge that the agency had previously applied the statute to disallow proposed state plan amendments that would have permitted States to set qualification standards unrelated to the provider's competence to perform medical services safely, legally, and ethically. The agency's unexplained departure from its prior practice thus adds little to this analysis. See *Encino Motorcars LLC v. Navarro*, 579 U.S. 211, 221-222 (2016). Cf. *Loper Bright Enterprises v. Raimondo*, 144 S. Ct. 2244, 2262 (2024).

[4] See *Planned Parenthood S. Atl. v. Baker*, 941 F.3d 687, 702 (4th Cir. 2019); *Planned Parenthood of Kans. v. Andersen*, 882 F.3d 1205, 1230 (10th Cir. 2018); *Planned Parenthood Arizona Inc. v. Betlach*, 727 F.3d 960, 969 (9th Cir. 2013); *Planned Parenthood of Indiana, Inc. v. Comm'r of Ind. State Dep't Health*, 699 F.3d 962, 978 (7th Cir. 2012). Cf. *O'Bannon v. Town Ct. Nursing Ctr.*, 447 U.S. 773, 786 (1980) ("we assume that [Section 1902(a)(23)] would

An individual or an entity that is capable of performing medical services in a professionally competent manner is therefore a "qualified" provider within the meaning of Section 1902(a)(23). This remains the case even if the individual or entity has delivered mifepristone or misoprostol through the mail or through a common carrier in reliance on the published opinion of the Office of Legal Counsel that these actions would not violate the Comstock Act in the absence of an intent that the drugs be used unlawfully. These actions do not call into question the provider's professional competence to perform the medical services that a Medicaid beneficiary would require, and so would be simply irrelevant in determining the provider's qualifications under Section 1902(a)(23). See *Planned Parenthood S. Atl. v. Baker*, 941 F.3d 687, 703 (4th Cir. 2019) ("To read the phrase as denoting anything other than fitness to perform the activity identified would be highly unusual.").

Section 1902(p)(1) does not change this analysis. As noted above, this provision preserves a State's authority to apply the sanction of exclusion from its Medicaid program to providers that have been convicted of certain criminal offenses or that have committed similar misconduct. The provisions referenced in Section 1902(p)(1) permit a State to exclude a provider on grounds of "professional malfeasance." *Baker*, 941 F.3d at 706 (collecting cases permitting exclusion on grounds such as "fraud or abuse," "financial self-dealing," and "shoddy record-keeping").

Many of the grounds listed under Section 1902(p)(1) and its cross-referenced provisions permit exclusion only after a provider has been convicted of a criminal offense or held liable for a civil monetary penalty. See 42 U.S.C. §§ 1320a-7(a), (b)(1)-(b)(3), 1320a-7a(a), 1395cc(b)(2)(D). An individual or entity who acts in reliance on the formally announced reading of federal law in a published opinion of the Office of Legal Counsel, however, would not properly be subject to prosecution under the Comstock Act. See *United States v. Pennsylvania Indus. Chem. Corp*., 411 U.S. 655, 674 (1973) ("*PICCO*") ("traditional notions of fairness inherent in our system of criminal justice prevent the Government from proceeding with the prosecution," where the defendant has acted in reliance on a formal opinion issued by "the responsible administrative agency" with the "designed purpose … to guide persons as to the meaning and requirements of the statute"). See also *Cox v. Louisiana*, 379 U.S. 559, 571 (1965) (due process prevents the government from "convicting a citizen for exercising a privilege which the [government] had clearly told him was available to him"); *Raley v. Ohio*, 360 U.S. 423, 426 (1959) (same).

The same result holds for each of the provisions described in Section 1902(p)(1), even if the State may otherwise permissibly apply those provisions to exclude an individual or entity from participation in the State plan in the absence of a criminal conviction or civil monetary penalty. Exclusion from participation in a heath care program is a "sanction[]," 42 U.S.C. § 1320a-7(b)(5), and the principles animating the *PICCO* line of cases would also apply to foreclose applying such a sanction under Section 1902(p)(1) against a Medicaid provider in cases where the regulated party has acted in reliance on a formal assurance, from a government official with the authority to provide such an assurance, that its conduct is lawful. At the very least, the

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prohibit any such interference with the patient's free choice among qualified providers").

Medicaid statute should not be read to countenance such a result unless its text certainly requires it. See *Jennings v. Rodriguez*, 583 U.S. 281, 296 (2018).

The grounds for exclusion referenced in Section 1902(p)(1) do not permit this result. For example, the Medicaid statute permits a State to exclude an individual or an entity from participation in its Medicaid plan if the State licensing authority has revoked or suspended the provider's license, or the individual or entity has been suspended or excluded from another federal or state health program, "for reasons bearing on the individual's or entity's professional competence, professional performance, or financial integrity." 42 U.S.C. § 1396a(p)(1) (incorporating *id.* § 1320a-7(b)(4), (5)). In cases where a provider has caused mifepristone or misoprostol to be mailed or otherwise delivered to a person, and the provider has done so in reliance on the published opinion of the Office of Legal Counsel that this conduct would not violate the Comstock Act, this conduct cannot be said to have any bearing on the provider's professional competence, professional performance, or financial integrity, as these terms are used in the Medicaid statute.[5] Similarly, although the Medicaid statute permits a State to exclude an individual or an entity from participation in its Medicaid plan if the provider "has furnished or caused to be furnished items or services to patients … of a quality which fails to meet professionally recognized standards of health care," 42 U.S.C. § 1396a(p)(1) (incorporating *id.* § 1320a-7(b)(6), a provider's mailing or delivery of a drug that the FDA has determined to be safe and effective, in reliance on an authoritative opinion of the Department of Justice that such conduct comports with federal law, could not reasonably be said to implicate whether the provider has performed medical services in accordance with professionally recognized standards of care within the meaning of the Medicaid statute.[6]

In sum, the Act permits a State to exclude a provider from participation under its State plan in cases where the provider is not capable of performing the required medical services in a professionally competent manner, or in certain cases where a provider has been convicted of a criminal offense or has committed certain forms of professional malfeasance. These grounds for exclusion are not implicated, however, where a provider mails or otherwise delivers these drugs under the circumstances described in OLC's opinion, and in reliance on that opinion. A State therefore may not seek to exclude a provider from participation under its State plan on the ground that the provider has purportedly violated the Comstock Act in such circumstances.

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[5] See generally the cases cited in note 4, *supra* (construing the analogous language under Section 1923(a)(23).

[6] Other provisions referenced in Section 1902(p)(1) are even further afield. See, *e.g.*, 42 U.S.C. §§ 1320a-7(b)(9) (permitting exclusion for a provider's failure to disclose required information); 1320a-7a(a)(10) (permitting exclusion for failure to return an overpayment); 1395cc(b)(20(A) (permitting exclusion in certain cases where a hospital subject to the Medicare Inpatient Prospective Payment System fails to comply with a required corrective action).

III. LIMITATIONS

This Advisory Opinion sets forth the current views of the Office of the General Counsel. It is not a final agency action or a final order.

Samuel R. Bagenstos - S

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