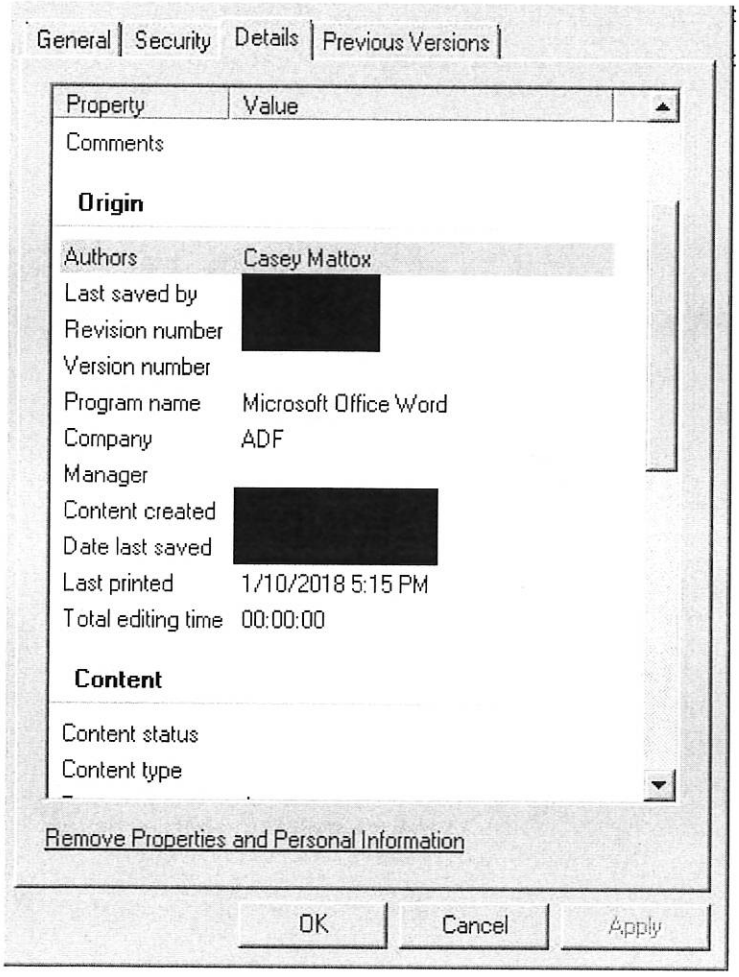
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January __, 2018

Dear State Medicaid Director:

The Center for Medicaid and CHIP Services (CMCS) and the Center for Program Integrity (CPI) are issuing this State Medicaid Director Letter to provide guidance to State Medicaid agencies concerning states' authority to design and operate their State Medicaid programs, including their authority to set standards related to provider licensing, qualifications and program participation, and how States can exercise that authority in a manner that is consistent with Section 1902(a)(23) of the Social Security Act, 42 U.S.C. § 1396a(a)(23) (any willing provider provision).

CMS issued prior guidance on the any willing provider provision on April 19, 2016. This guidance letter supersedes that letter, and provides greater clarity regarding state regulation of provider qualifications under the any willing provider provision.

Background

Medicaid is jointly funded by the State and Federal governments, and the States are responsible for operating their own State Medicaid programs within Federal guidelines. Each State develops its own Medicaid plan to serve the needs of its citizens. The Medicaid program guarantees States "flexibility in designing plans that meet their individual needs" and "considerable latitude in formulating the terms of their own medical assistance plans." *Addis v. Whitburn,* 153 F.3d 836, 840 (7th Cir. 1998) (citing *Dandridge v. Williams,* 397 U.S. 471, 487 (1970)). States enjoy "considerable autonomy" under Medicaid to "select dramatically different levels of funding and coverage, alter and experiment with different financing and delivery modes, and opt to cover (or not to cover) a range of particular procedures and therapies. States have leveraged this policy discretion to generate a myriad of dramatically different Medicaid programs over the past several decades." *Nat'l Fed. Of Ind. Bus. v. Sebelius,* 132 S.Ct. 2566, 2632 (2012) (Ginsburg, J., concurring in part and dissenting in part).

Of course, States must adhere to a number of Federal requirements in operating their Medicaid programs. One such requirement is the "any willing provider" provision (also referred to as the "free choice of provider" provision), which requires State plans for medical assistance to allow beneficiaries to "obtain such assistance from any institution, agency, community pharmacy, or person, qualified to perform the service or services required . . ., who undertakes to provide him such services…" 42 U.S.C. § 1396a(a)(23).[1] There is an exception for beneficiaries enrolled in certain managed care plans (to permit such plans to restrict beneficiaries to providers in the managed care network), except that such plans cannot restrict freedom of choice with respect to qualified providers of family planning services. *Id.*

State Authority to Determine Provider Qualifications

A State's legal authority to regulate healthcare providers derives from a variety of sources, not the least of which is the U.S. Constitution, which reserves the State's police power through the 10th Amendment. The police power is generally recognized as the capacity of States to regulate behavior within their territory for the betterment of the health, safety, morals, and general

[1] The provision does not apply in Puerto Rico, the Virgin Islands, and Guam.

welfare of their inhabitants. While this authority may be limited by other constitutional rights or by operation of Federal law, the laws and regulations governing Federal healthcare programs recognize and preserve the States' role in matters such as licensure of medical professionals and facilities and allow States considerable flexibility to design and operate their Medicaid programs.

As relevant to the Medicaid program, Federal law grants express power to the State to exclude providers "for any reason for which the Secretary could exclude the [provider] from participation in [the Medicare program]." 42 U.S.C. § 1396a(p)(1). This exclusion authority extends to reasons related to program-related offenses and convictions, *see, e.g.,* 42 U.S.C. §1320a-7 (enumerating grounds for mandatory and permissive exclusions), as well as the termination of a provider's Medicare agreement. §1395cc(b)(2). Importantly, Federal law also expressly recognizes the State's power to exclude providers under "any other authority." 42 U.S.C. § 1396a(p)(1). This has been interpreted to mean that a State may establish, under State law, other bases for excluding providers from its Medicaid program. *First Med. Health Plan v. Vega-Ramos,* 479 F.3d 46, 53 (1st Cir. 2007).[2]

CMS regulations also explicitly recognize the States' traditional role of setting "reasonable standards relating to the qualifications of providers." 42 C.F.R. § 431.51(c)(2). In fact, CMS determinations regarding participation in (or payment under) the Medicare program often rely on a providers' compliance with State and local laws. *See, e.g.*, 42 C.F.R. § 484.115 (personnel qualifications for Medicare home health professionals); 42 C.F.R. § 485.54 (condition of participation for comprehensive rehabilitation facilities); 42 C.F.R. § 485.707 (condition of participation for outpatient physical therapy and speech-language pathology providers); 42 C.F.R. § 485.608 (condition of participation for critical access hospitals).

Any Willing Provider Provision

CMS issued prior guidance on this provision on April 19, 2016 in an effort to clarify which State regulatory enforcement actions are permissible under section 1902(a)(23) of the Social Security Act. Since CMS issued this guidance, several States have requested further clarification on how to comply with the any willing provider provision while still exercising the States' longstanding authority to regulate matters affecting the health, safety, morals, and general welfare of their citizens. This letter provider that clarification, and supersedes the April 19, 2016 letter.

First, we note that the statute on its face only requires that States enable beneficiaries to receive services from any "*qualified*" provider that is willing to provide the services sought, and explicitly permits states to exclude providers that have been "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." 42 U.S.C. § 1396a(a)(23). The provision would therefore not require a State to allow beneficiaries access to providers that it has determined are "unqualified," or that have been convicted of a felony offense. CMS regulations confirm this interpretation, and

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[2] The legislative history of the Medicaid Act also rejects any narrower construction.

> "The Committee bill clarifies current Medicaid Law by expressly granting states the authority to exclude individuals or entities from participation in their Medicaid programs for any reason that constitutes a basis for an exclusion … This provision is not intended to preclude a state from establishing, under state law, any other bases for excluding individuals or entities from its Medicaid program."

S. Rep. 100-109, reprinted in 1987 U.S.C.C.A.N. at 700).

stipulate that the any willing provider provision does not prohibit the State Medicaid agency from "setting reasonable standards related to the qualifications of providers." 42 C.F.R. § 431.51(c)(2).

Beyond the standards that exist in federal law, states are in the best position to determine what additional protections may be reasonable and necessary to protect the health and welfare of their citizens and the fiscal integrity of the program. For instance, states may reasonably promulgate and enforce standards that relate to a provider's ability to perform the services in question in a professionally competent, safe, legal and ethical manner. States are also expected to develop and enforce rules that protect the fiscal integrity of the Medicaid program and protect against improper payments. The any willing provider provision would not prevent a state, for instance, from instituting measures to protect program funds from being spent on unallowable expenses (e.g., by requiring accounting and segregation of funds spent on covered and non-covered services), and taking action against a provider or class of providers that fail to comply with those measures.

Second, the statute does not restrict a State's authority to withhold, suspend or revoke permits, licenses, certificates, privileges, or any other credentials the State or its localities require as a prerequisite to operating a business or performing healthcare services, based on noncompliance with State or local rules. For instance, if a State is aware that an applicant for credentials or licensure is subject to ongoing investigation, the State may deny or delay the request pending the outcome of the investigation.

Given the broad deference the statute grants the States, CMS believes that States should have considerable flexibility in establishing rules that ensure that healthcare providers in their jurisdictions are capable of performing medical services in a professionally competent, safe, legal and ethical manner, and do not pose a threat to program integrity. In taking enforcement actions under these rules, where such enforcement action results in restricting a Medicaid beneficiary's access to an otherwise willing provider, we would expect States to be able to articulate a rational connection between the restriction and (a) the provider's capacity or qualifications to perform services in a safe, legal and ethical manner, (b) program integrity objectives, or (c) other legitimate objectives. CMS will afford considerable deference to States in this regard.

Finally, we also wish to clarify that the any willing provider provision does not define a State's obligation to ensure that beneficiaries have adequate access to care. The any willing provider provision at 42 U.S.C. § 1396a(a)(23) is separate and distinct from what is known as the access rule at 42 U.S.C. § 1396a(a)(30)(A), which requires States to set payment rates at levels that are "sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area." The 2016 State Medicaid Director letter alluded to a "longstanding CMS policy that Medicaid beneficiaries are provided with competent care by qualified providers and have the same ability to choose among available providers as those with private coverage." We think it is important to clarify that while the Medicaid access rule is designed to assure beneficiaries have adequate access to needed healthcare services, we do not interpret the any willing provider provision as independently imposing a network adequacy standard.

Conclusion

Notwithstanding section 1902(a)(23) of the Social Security Act, States may establish provider standards and take enforcement action under those standards, even when such enforcement impacts beneficiary access to those providers, where such standards reasonably relate to (a) the provider's capacity or qualifications to perform services in a safe, legal and ethical manner, (b) program integrity objectives, or (c) other legitimate objectives.

CMS is available to work closely with each State to ensure compliance with Medicaid's "any willing provider" provision with the goal of preserving States' longstanding authority to regulate matters of health, safety, morals, and general welfare. If you have any questions regarding this information, please contact [_____]

Sincerely,

Brian Neale

Director, CMCS

Alec Alexander

Director, CPI