CENTERS FOR MEDICARE AND MEDICAID SERVICES

Decision of the Administrator

In the matter of:

The Disapproval of the Indiana State Plan Amendment SPA 11-011

Docket No. 11-03
Dated: June 20, 2012

This case is before the Administrator, Centers for Medicare & Medicaid Services (CMS), for review pursuant to 42 CFR 430.102. The State of Indiana requested reconsideration of the Administrator's disapproval of the Indiana State Plan Amendment (SPA) 11-011. The CMS Presiding Officer's recommended decision was issued on June 20, 2012, affirming the Administrator's disapproval. The parties timely filed exceptions to the CMS Presiding Officer's recommended decision.

Issue

The issue is whether the State of Indiana's proposed SPA 11-011 complied with the requirements of section 1902(a)(23) of the Social Security Act.

Background

The State of Indiana House Enrolled Act (HEA) 1210, was signed into law on May 10, 2011. The House Enrollment Act (HEA) is codified at Indiana Code [IC] §5-22-17-5.5, titled, "Applicability; prohibition on State contracts and grants with entities that perform abortions; appropriations; termination of contract" and states that:

> Sec. 5.5. (a) This section does not apply to hospitals licensed under IC 16-21-2 or ambulatory surgical centers licensed under IC 16-21-2.

> (b) An agency of the state may not: (1) enter into a contract with; or (2) make a grant to; any entity that performs abortions or maintains or operates a facility where abortions are performed that involves the expenditure of state funds or federal funds administered by the state.
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> (c) Any appropriation by the state: (1) in a budget bill; (2) under IC 5-19-1-3.5; or (3) in any other law of the state; to pay for a contract with or grant made to any entity that performs abortions or maintains or operates a facility where abortions are performed is canceled, and the money appropriated is not available for payment of any contract with or grant made to the entity that performs abortions or maintains or operates a facility where abortions are performed.
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> (d) For any contract with or grant made to an entity that performs abortions or maintains or operates a facility where abortions are performed covered under subsection (b), the budget agency shall make a determination that funds are not available, and the contract or grant shall be terminated under section 5 of this chapter.[1]

By letter dated May 13, 2011, the State of Indiana Office of Medicaid Policy and Planning (OMPP) (hereafter referred to as the State) submitted SPA 11-011 to CMS.[2] The cover letter explained that:

> This State Plan amendment seeks to make a change to Indiana's State plan in order to conform to Indiana State law. The attached page adds a new qualification that must be met in order for a provider to participate in the Medicaid program.

The attached page, proposing to supersede State Plan section 4, page 45.1, stated that:

> 42 CFR 431.107[[3]] (e) No contract or grant can be entered into with providers that perform abortions or maintain or

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[1] The Planned Parenthood of Indiana filed in the United States District Court for the Southern District of Indiana and was successful in seeking a preliminary injunction to enjoin defendant from enforcing the law. *See Planned Parenthood, Inc. v. Commissioner of the Indiana State Department of Health*, 794 F. Supp. 2d 892 (S. D. Ind..)(June 24, 2011), 699 F.3d 962 (7th Cir. Oct. 23, 2012).

[2] CMS Exhibit 2.

[3] The regulation at 42 CFR 431.107 addresses "Required provider agreement" and includes State plan requirements, based on sections 1902(a)(4), 1902(a)(27), 1902(a)(57), and 1902(a)(58) of the Act, that relate to the keeping of records and the furnishing and disclosing

> operate facilities where abortions are performed, except for hospitals licensed under Indiana Code 16-21-2 or ambulatory surgical centers, licensed under Indiana Code 16-21-21.

In sum, the State of Indiana proposed to amend the State plan to prohibit State agencies from entering into contracts or grants with providers that perform abortions or maintain or operate facilities where abortions are performed, but excepted hospitals and ambulatory surgical centers from this provision.

The Indiana Legislative Services Agency has the role of bill drafting and fiscal, budgetary and management analysis on behalf of State legislature and issued a Report regarding HEA 1210, which explained:

> "(Revised) It is uncertain how the contracting prohibitions contained in the bill will interact with federal regulations concerning the Medicaid program. While the Medicaid provider agreement is a contract, federal regulations appear to make it unlikely that the bill could impact Planned Parenthood's ability to bill for Medicaid services. .... Assuming the Office of Medicaid Policy and Planning (OMPP) cannot implement the provisions of the bill (due to federal supremacy), there would be no effect and no fiscal impact on state expenditures for Medicaid and provider contracts.
> **** (Revised) The Family and Social Services Administration reports that federal law requires state Medicaid plans to provide any eligible individual medical assistance and that they can obtain such assistance from any institution, agency, community pharmacy, or person, qualified to perform the service(s) required. This also includes an organization which provides such services, or arranges for their availability, on a prepayment basis. Federal law permits states to define a qualified provider, but requires that this definition is related to a provider's ability to perform a service and not what services are provided. While states are permitted to waive a recipient's freedom of choice of a provider to implement managed care, restricting freedom of choice with respect to providers of family planning services is prohibited."[4]

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of information by all providers of services (including individual practitioners and groups of practitioners).

[4] *See also* Presiding Hearing Officer recommended decision at n. 26 and n.27 discussing the role of the Indiana Legislative Services Agency. The Fiscal impact statement is at: http://www.in.gov/legislative/bills/2011/PDF/FISCAL/HB1210.009.pdf

By notice, dated June 1, 2011, the Administrator notified the State of Indiana that the SPA 11-011 was disapproved.[5] The Administrator's disapproval letter stated that section 1902(a)(23)(A) of the Act provides that beneficiaries may obtain covered services from any qualified provider that undertakes to provide such services. This SPA would eliminate the ability of Medicaid beneficiaries to receive services from specific providers for reasons not related to their qualifications to provide such services. The Administrator explained that, as the State was aware, Federal Medicaid funding of abortion services is not permitted under Federal law except in extraordinary circumstances (such as in cases of rape or incest). At the same time, Medicaid programs may not exclude qualified health care providers from providing services that are funded under the program because of a provider's scope of practice. Such a restriction would have a particular effect on beneficiaries' ability to access family planning providers, as access to these providers is subject to additional protections under section 1902(a)(23)(B) of the Act. These protections also apply in managed care delivery systems. Therefore, the Administrator found that he could not determine that the proposed amendment complies with section 1902(a)(23) of the Act. The Administrator noted that it was assumed this decision was not unexpected. As the Indiana Legislative Services Agency indicated in its April 19, 2011 fiscal impact statement, "While States are permitted to waive a recipient's freedom of choice of a provider to implement manage care, restricting freedom of choice with respect to providers of family planning services is prohibited."[6]

CMS also subsequently issued a "Medicaid Informational Bulletin," dated June 1, 2011, which stated that the: "Medicaid program may not exclude qualified health care provider ... from providing services under the program because they separately provide abortion services (not funded by federal Medicaid dollars, consistent with the federal prohibition) as part of their scope of practice."

By letter dated June 15, 2011, the State of Indiana's Family and Social Services Administration (FSSA) issued a "Notice of Intent to Adopt a Rule (Notice) permitting Affiliates of Abortion Providers to be Medicaid Providers" (Notice of Intent). The 'Notice of Intent" stated that it was issued to clarify that HEA 1210's reference to:

> any entity that performs abortions or maintains or operates a facility where abortions are performed," under [HEA 1210] does not include a separate affiliate of such entity, if the entity does not benefit, even indirectly, from government contracts or grants awarded to the separate affiliate.[7]

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[5] State Exhibit 1.

[6] State Exhibit 2.

[7] State Exhibit 8.

The State of Indiana requested that CMS reconsider the June 1, 2011 disapproval.[8] By letter dated July 20, 2011, CMS reiterated that section 1902(a)(23) of the Act prohibited Medicaid programs from excluding qualified providers from providing covered services on the basis of a provider's scope of practice. CMS gave notice that the State of Indiana would be provided an administrative hearing regarding the State of Indiana's request that CMS reconsider the disapproval of SPA 11-011.[9] A *Federal Register* Notice of Hearing was published asserting the basis for the SPA disapproval and appointing the CMS Presiding Officer and setting forth details on the administrative hearing.[10] The parties briefed the issue, a hearing was held and the parties were allowed to submit post-hearing briefs on the issue.[11]

CMS Presiding Officer's Recommended Decision

The CMS Presiding Officer's recommended decision held that the CMS disapproval of the State of Indiana's SPA 11-011 was correct. The Presiding Officer first found that the regulations require that State plans be comprehensive in describing the nature and scope of the Medicaid program and contain all information necessary for CMS to determine whether the State plan (and State plan amendments) can be approved. The Presiding Officer found that the May 2011 written SPA submission did not notify CMS that the State was contemplating a separate "affiliate option." Accordingly, as such an option was not effectively presented, CMS could not reasonably be expected to consider and review such an option prior to issuing the June 1, 2011 disapproval. Because CMS was not provided an opportunity to consider the affiliate option, the Presiding Officer determined he would not address the issue of whether or not a SPA that prohibits contracting with entities that provide abortion services could potentially satisfy the requirements of section 1902(a)(23) of the Act by means of a separate affiliate provision.

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[8] CMS Presiding Officer Recommended Decision at 2; State Prehearing Memorandum at 3.
[9] State Exhibit 3.
[10] 76 Fed. Reg. 44591 (July 26, 2011) ("Centers for Medicare & Medicaid Services Notice of Hearing: Reconsideration of Disapproval of Indiana State Plan Amendment (SPA) 11-011.")
[11] The Planned Parenthood of Indiana filed an amicus curiae petition before the Presiding Officer. The Presiding Officer determined that, under the controlling regulatory criteria at 42 CFR 430.76, the petition should be placed into the administrative record with the caveat that the State's inability to confront the petitioner at the proceedings would be a factor in weighting any assertions that may ultimately impact the findings of the tribunal. Subsequently, the Presiding Officer (Recommended Decision n. 59), determined that the ultimate legal issue was one of statutory construction that is resolved without the required findings relating to any single provider (citing Recommended Decision at 17-22). In addition, the Presiding Officer determined that the issue of assigning weight to the amicus curiae petition was moot.

The Presiding Officer next reviewed whether a State plan may deny Medicaid recipients the discretion to obtain covered services from their provider of choice because such entity is deemed categorically not qualified on the basis that it performs non-covered abortion procedures. The Presiding Officer determined that SPA 11-011 was contrary to the plan language of the "free choice of provider" provision at section 1902(a)(23) of the Act as the self-contained text of the free choice of provider provision unambiguously resolves the dispute. The Presiding Officer found that section 1902(a)(23) generally grants Medicaid individuals full discretion to self-select their own providers for the covered services that they may require with the condition that the provider must be qualified. The "qualified" criterion protects individuals who may not have access to the means to make informed decision regarding a provider's fitness to perform care and services. While States share the responsibility and discretion in setting and enforcing qualifications of their providers, a provider's qualifications are based upon the actual performance of the service or services. The relevant service or services at issue are family planning services. The State does not argue that providers affected by the SPA are unfit to provide such services under its Medicaid program, but rather these providers could otherwise be allowed to provide these same services, if either they ceased performing abortions in the scope of their non-Medicaid covered practice, or created a separate fiscal entity.

The Presiding Officer found that SPA 11-011 violated the plain text of section 1902(a)(23) of the Act, because it restricts individuals from obtaining covered family planning services from entities that are fit to provide and deliver such services. The Presiding Officer stated that States may have the prerogative to set fitness standards directly and/or indirectly tied to the ultimate delivery of covered services (*e.g.*, protection of beneficiaries from convicted criminals). However, the descriptive text "qualified to perform the service or services required" prohibits the government from restricting patients' discretion to appropriately select their own provider of choice on the basis that such provider practices other (non-covered) services.

The Presiding Officer found that, as the text linking provider qualifications to the performance of the service or services required was unambiguous, the State's reliance on *Pennhurst State School & Hospital v. Halderman*, 451 U.S. 1 (1981), ("the clear statement rule" and whether the State voluntarily and knowingly accepts the terms of the contract), was misplaced. The Presiding Officer pointed to the legislative history of HEA, which clearly indicated that the Indiana Legislative Services Agency was aware of the scope of the free choice of provider requirement and the use of the term "qualified" as it relates to a "provider's ability to perform a service and not what services are provided" and that waiving recipient's freedom of choice of a provider is prohibited for family planning services.

The Presiding Officer also rejected the State's contention that only a small number of providers are affected and that a State may establish a plan that may "incidentally" reduce the number of available providers. The Presiding Officer acknowledged that baseline

qualification standards may reduce the number of providers and not automatically violate section 1902(a)(23) of the Act. However, SPA 11-011 violates section 1902(a)(23), because it squarely restricts individuals from obtaining Medicaid covered services from entities that are otherwise fit to provide such services.

The Presiding Officer also disagreed with the State's contention that section 1902(p)(1) of the Act empowered States to establish a wide range of provider qualifications. The Presiding Officer found that section 1902(p)(1) of the Act was designed to focus on program-related offenses and quality of care, as opposed to establishing broad qualification standards based on the types of services rendered as exemplified by the reference to sections 1128, 1128A or 1866(b)(2) of the Act. The incorporation of these cross-references clarifies that the "exclusionary" authority granted the States under this section is to be used to exclude providers whose quality of care or billing practices place beneficiaries or the integrity of the Medicaid Program at risk. These provisions do not contemplate the exclusion based upon a range of non-covered services offered. Section 1902(p)(1) defines "exclude" to include the refusal to enter into or renew a participation agreement. "Exclude" is used as a singular, provider-focused organizationally-focused term and, as CMS regulations contemplate, on a case-by case basis, with due process to the provider such as the process under 42 CFR Part 1000, *et seq.*. Likewise, the legislative history of section 1902(p)(1) of the Act does not support the State's contention. Therefore, the authority granted to States under section 1902(p)(1) is intended as a State level analogue to the types of powers granted the Secretary with regard to the specified statutory provisions only.

The Presiding Officer concluded that SPA 11-011, based upon HEA 1210, is contrary to the plain language of the free choice of provider requirement at section 1902(a)(23) of the Act. The issue of whether SPA 11-011 can be salvaged if it had expressly included an affiliate option was not before this administrative tribunal. The Presiding Officer found that section 1902(p)(1) of the Act does not apply, because it addresses exclusionary powers over specific individuals or entities. Therefore, the CMS decision to disapprove SPA 11-011 was correct.

<u>Summary of Exceptions</u>

The State submitted exceptions to the Presiding Officer's recommended decision. The State requested that, on reconsideration, the Administrator approve SPA 11-011. The State argued that the Presiding Officer erred in refusing to consider the State's "Notice of Intent to Adopt a Rule Permitting Affiliates of Abortion Providers to be Medicaid Providers." The State argued that the regulation at 42 CFR 430.88 contemplates the submission of additional evidence and the Presiding Officer erred in not considering the State's Notice of Intent. The State explained that CMS and the Administrator have been duly notified that the State is considering an affiliate option; the Notice of Intent is part of the record; and its significance was discussed in multiple briefs and in the Transcript of the Oral Hearing. It would, in effect, violate 42 CFR 430.88 (permitting the creation of a post-denial administrative

record), for CMS to ignore the Notice of Intent on the grounds that the Notice was not presented with the SPA in the first instance. For the sake of giving legal and practical effect to that regulation, not to mention facilitating final appellate review of the State's statute and SPA, CMS should consider the legal significance of the Notice of Intent. (State's Exceptions, Part I, pp 1-6.)

Next, the State argued that the Presiding Officer's statutory interpretation of the term "qualified" was unsupported by anything, except policy preferences. The Presiding Officer failed to offer a legal reason why baseline fitness might, at the designation of a State legislature, permissibly include a provider's criminal record without limitation, but not the provider's use of Medicaid funds to cross-subsidize abortions. The State argued that common usage of the term "qualification" was not limited to just licensure, quality of care, and criminal record, but also included instances when qualification was defined in terms of financial integrity and ethical conduct. The SPA 11-011 easily fit, the State alleged, within the broad understanding that "qualifications" can include any requirement to adhere to State policy. The SPA also related more narrowly to fiscal integrity by preventing taxpayer subsidy of abortions. The State also analogized this provision to qualifications based on billing practices and that the SPA excludes abortion providers because of their billing practices. The foregoing fiscal integrity argument was not specifically addressed by the Presiding Officer. (State's Exceptions, Part II, para. 1. pp. 6-7.)

In addition, while the Presiding Officer set the parameters of the term "qualification" as based upon the actual performance of the service or services required, the decision refers only to a general statutory phrase and still begs the questions of what it means to be "qualified" to perform those services and whether these qualifications can reasonably include matters as ethical, financial and legal considerations, criminal convictions for actions unrelated to family planning services or the range of other services carried out by the provider that might be indirectly funded or cross-subsidized by Medicaid. The State claimed there is no statutory basis for declaring that the State may exclude a provider for acting contrary to public policy embodied in criminal law, but not for public policy embodied in a civil law and, therefore, is only a policy preference. If Congress intended to limit qualifications to licensure, quality of care and criminal records, it could have said as much, but did not. Thus, those categories are not entitled to special status as a matter of law. (State's Exceptions, Part II, para. 2. pp. 7-8.)

Furthermore the State contended that the precedents the State included in the record (Exhibits 12-14, 16-18.) are contrary to the Presiding Officer's interpretation of the use of the term "qualified" in the statute. The Presiding Officer recognized there can be a reduction in available providers due to baseline standards, that does not automatically violate section 1902(a)(23), yet he claims that the SPA impermissibly restricts patient access to providers, because it squarely restricts individuals from obtaining Medicaid covered services from entities otherwise fit to provide such services. The State contended that, neither the

proposed SPA, nor HEA 1210, eliminates any providers. For current Medicaid providers who are also abortion providers, the SPA provides a choice to elect to be one or the other. Such a result is not dictated by State law, or the SPA. Furthermore, an affiliate option outlined in the Notice of Intent would likely help reduce the choices made in light of HEA 1210 and SPA 11-011. Thus, the contingent nature of these matters underscores that SPA 11-011 does not squarely restrict patient choice. (State's Exceptions, Part II, para. 3. pp. 8-9.)

A hypothetical incidental impact on individuals in no way distinguishes SPA 11-011. The recommended decision acknowledged that individuals are often incidentally restricted from obtaining Medicaid covered services from providers that are otherwise fit to provide such services for any number of reasons. (*See* Exhibits 12, 13 showing incidental restrictions.) The recommended decision should have adopted the reasoning set forth in *Kelly Kare, Ltd v. O'Rourke,* 930 F2d 170, 178 (2d Cir. 1991)(which allowed upholding termination of a provider agreement notwithstanding lost choice as it was a mere incidental burden of the right to choose under section 1902(a)(23) of the Act). The State also claimed that the precedents the State has included in the record were not distinguished by the Presiding Officer except to the extent it claimed that they are uniquely factually and legally distinguishable. The only way to distinguish the SPA from these cases/State plans is based on policy preference. (State's Exceptions, Part II, para. 3. pp. 9-10.)

The State also contended that the SPA 11-011 meets the Presiding Officer's preferred application of the term "exclude" in section 1902(p)(1) of the Act. The Presiding Officer found that "exclude", under section 1902(p)(1) of the Act, can be applied only in a "singular, provider-focused or organizational terms." This includes, for example, the exclusion of providers who refuse "to enter into or renew participation agreement or the termination of such an agreement." However, the SPA and HEA provides that a State may not enter into a provider agreement with any entity that performs abortions or maintains or operates a facility where abortions are performed. The SPA focus is on the conduct of an entity and is "singular" and "organization-focused." The SPA would provide a case-by-case review, consistent with due process, whenever there is a disagreement on whether a Medicaid provider performs abortions or maintains a facility where abortions are performed, were it implemented. (405 Ind. Admin. Code 1-1.5)[12] (State's Exceptions, Part III, p. 11.)

[12] http://www.in.gov/legislative/iac/T04050/A00010.PDF
See 405 IAC 1-1.5-1 ("Sec. 1. (a) This rule governs the procedures for appeals to the office of Medicaid policy and planning (office) involving actions or determinations of reimbursement for all Medicaid providers. (b) This rule governs the procedures for appeals to the office from the following actions or determinations: (1) Setting rates of reimbursement. (2) Any action based upon a final audit. (3) Determination of change of provider status for purposes of setting a rate of reimbursement. (4) Determination by the office that an overpayment to a provider has been made due to a year-end cost settlement.

The Presiding Officer also incorrectly dismissed the legislative history supporting SPA 11-011. The State claimed that the Senate Report 100-109 unambiguously states that section 1902(p)(1) is not intended to preclude a State from establishing under State law, any other bases for excluding individuals or entities from its Medicaid program. The Senate Report draws a distinction between what it bestows and what it preserves, with the bestowal being considerably narrower than the preservation. The preservation clause is not simply to restate the power authorized by the bestowal clause, but instead to disclaim the very sort of implied preemption the recommended decision now urges. The recommended decision does not specify what the preservation of other bases for exclusion might possibly mean in context. (State's Exceptions, Part IV, p. 13.)

Finally, the State maintained that the Presiding Officer's interpretation of section 1902(p)(1) of the Act conflicts with the regulation at 42 CFR 1002.2(b). The recommended decision does not reconcile the regulations which expressly provides that "nothing contained in this part [regarding State initiated exclusions from Medicaid] should be construed to limit a State's own authority to exclude an individual or entity from Medicaid for any reason or period authorized by State law." The recommended decision only refers to the placement as underscoring the fraud and abuse context of this provision, as it is included among the OIG operating regulations. However, the State maintained that the reliance on the placement, instead of the text, is insufficient to neutralize section 1002.2(b), as these regulations specifically authorize State agencies to exclude on their own initiative. Nothing in this language limits a State to exclusions based on fraud and abuse. The placement in the OIG regulations is logical, as that is the entity that enforces the Federal exclusion being enumerated. In addition, the State maintained that SPA and HEA were established to prevent abuse of Medicaid insofar as it has been used to cross-subsidize abortions. The Administrator should adopt the plain text of the regulations. (State's Exceptions, Part V, pp. 13-14.)

Therefore, the State argued that, even if section 1902(a)(23) of the Act conferred rights to individual beneficiaries, the States have the authority to establish providers' qualifications that indirectly limits Medicaid beneficiaries "freedom of choice" so long as the included

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(5) Any other determination by the office that a provider has been paid more than it was entitled to receive under any federal or state statute or regulation. (6) The office's refusal to enter into a provider agreement. (7) The office's suspension, termination, or refusal to renew an existing provider agreement. (c) Notwithstanding subsections (a) and (b), this rule does not govern determinations by the office or its contractor with respect to the authorization or approval of Medicaid services requested by a provider on behalf of a recipient. (d) Disputes relating to claims submitted to a managed care organization (MCO) by providers who are not under contract to the MCO, and who provide services to recipients in the risk-based managed care program are governed by 405 IAC 1-1.6.")

requirement adheres to State policy. To support this position, the State relied on section 1902(p)(1) of the Act. The State maintained that it may permissibly expel from the Medicaid program, providers that are undisputedly "qualified to perform the service or services required", because such providers, apart from their Medicaid practice, also perform non-covered services of which the State disapproves.

CMS submitted exceptions agreeing with the State's contention that the Presiding Officer should have considered, as evidence, the State's "Notice of Intent" that would purportedly addressed an affiliate option, but that it was harmless error. CMS stated that the regulations at 42 CFR Part 430, Subpart D contemplated the submission of additional evidence before the Presiding Officer. However, while it was proper for the State of Indiana to submit the Notice of Intent as evidence during the reconsideration process, the Notice of Intent was insufficient to bring SPA 11-011 into compliance with the "free choice of provider" provision at section 1902(a)(23) of the Act. CMS stated that the SPA 11-011 was not binding and did not provide a mechanism through which affected qualified providers could continue to participate in the Medicaid program, while maintaining their scope of practice. Therefore, any reliance upon a hypothetical affiliate scheme could not save the SPA 11-011 from being in conflict with section 1902(a)(23) of the Act.

In response to CMS exceptions, the State argued that the Presiding Officer's error cannot be viewed as harmless error, as the Administrator issues his or her own final decision. However, both the State and CMS agree that the Presiding Officer did not give proper consideration to the Notice of Intent. Thus, the State maintained it would be improper to adopt the recommended decision unaltered. Rather, the Administrator should issue a decision that discusses the legal significance of the Notice of Intent. However, the State maintained that the Notice of Intent is helpful, but not critical, to the State's legal argument supporting the SPA. It provides some indication of how HEA 1210 and SPA 11-011 would likely be implemented and it underscores the point that SPA 11-011 does not necessarily disqualify any Medicaid providers. Rather, SPA 11-011 gives current and prospective Medicaid providers a choice between providing Medicaid covered services and abortion services. The Notice of Intent raises the possibility that providers may be able to manage that choice by constructing financially independent relationships with affiliates that provide abortion services; an outcome that would further reduce the likelihood that SPA 11-011 will lead to any incidental reduction in providers. In short, the SPA 11-011 cannot be rejected on the theory that it will necessarily deprive some patients of their first choice provider.

The State also claimed that, more broadly, questions about the incidental effects of SPA 11-011 on the providers available to patients are immaterial. Section 1902(a)(23) requires State plans to permit recipients free choice among qualified providers and section 1902(p)(1) of the Act authorizes States to determine qualifications. The result is that, while States may not target recipients' choice as such, they may employ a large variety of Medicaid qualifications, rules and reimbursement policies, which incidentally affect the range of

patient choices amount providers. Because the SPA does not directly target patient choice, the State argued that it does not run afoul of the free choice of provider rule.

Discussion

The entire record, which was furnished by the CMS Presiding Officer, has been examined, including all correspondence, position papers, Transcript of Oral Hearing, and exhibits. The Administrator has reviewed the Presiding Officer's recommended decision. All exceptions received are included in the record and have been considered.

Medicaid State Plans

The Medicaid program, enacted in 1965 as Title XIX of the Act, is a cooperative Federal-State program created to provide 'medical assistance" to eligible low income families and individuals.[13] The program is jointly financed by the Federal and State governments and is administered by the States.[14] Section 1901 of the Act provides that for the purpose of enabling each State, as far as practicable under the conditions in such State, to furnish (1) "medical assistance" on behalf of families with dependent children and of aged, blind, or disabled individuals, whose income and resources are insufficient to meet the costs of necessary medical services, and (2) rehabilitation and other services to help such families and individuals attain or retain capability for independence or self-care, Federal appropriation are authorized for each fiscal year, that is sufficient to carry out the purposes of this title. The sums made available under this section "shall be used for making payments to States which have submitted, and had approved by the Secretary, State plans for medical assistance."

While participation in the program is voluntary, those participating States must comply with requirements imposed by the Act and regulations promulgated by the Secretary of Health and Human Services (Secretary).[15] States that opt to participate in the Medicaid program

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[13] Section 1902 of the Act.

[14] *See* Section 1901 and 42 C.F.R. 430.0 which states that: "Title XIX of the Social Security Act, enacted in 1965, authorizes Federal grants to States for medical assistance to low-income persons who are age 65 or over, blind, disabled, or members of families with dependent children or qualified pregnant women or children. The program is jointly financed by the Federal and State governments and administered by States. Within broad Federal rules, each State decides eligible groups, types and range of services, payment levels for services, and administrative and operating procedures. Payments for services are made directly by the State to the individuals or entities that furnish the services."

[15] Section 1902 of the Act.

must submit a comprehensive plan for the provision of medical assistance services that must be approved by the Secretary.[16] The regulation at 42 CFR 430.10 explains that:

> The State plan is a comprehensive written statement submitted by the agency describing the nature and scope of its Medicaid program and giving assurance that it will be administered in conformity with the specific requirements of title XIX, the regulations in this Chapter IV, and other applicable official issuances of the Department. The State plan contains all information necessary for CMS to determine whether the plan can be approved to serve as a basis for Federal financial participation (FFP) in the State program.

The Secretary delegates power to review and approve State plans to CMS.[17] CMS reviews the State plan to determine whether its provisions are consistent with Federal law and policy. CMS exercises its delegated authority either to approve or, after consulting with the Secretary, to disapprove the State plan.[18] Once CMS approves a State Medicaid plan, the Federal government shares in the cost of providing medical assistance under the program also referred to as Federal financial participation or FFP. The cost allocation, under the Medicaid program, is calculated by applying the 'Federal medical assistance percentage" or "FMAP" to the Federal government share of the Medicaid costs and by law is determined under section 1905(b) of the Social Security Act in conjunction with section 1903 of the Act ("Payment to States").

The regulations at 42 CFR 430.12(c) also provides that a State must, under certain circumstances, amend its plan:

> (1) The plan must provide that it will be amended whenever necessary to reflect—
> (i) Changes in Federal law, regulations, policy interpretations, or court decisions; or
> (ii) Material changes in State law, organization, or policy, or in the State's operation of the Medicaid program. For changes related to advance directive

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[16] Section 1116 of the Act.

[17] 42 CFR 430.15 explains that: "(a) Basis for action.(1) Determinations as to whether State plans (including plan amendments and administrative practice under the plans) originally meet or continue to meet the requirements for approval are based on relevant Federal statutes and regulations. (2) Guidelines are furnished to assist in the interpretation of the regulations. *** (c) Disapproval authority.(1) The Administrator retains authority for determining that proposed plan material is not approvable or that previously approved material no longer meets the requirements for approval. (2) The Administrator does not make a final determination of disapproval without first consulting the Secretary."

[18] *See* 42 CFR 430.15(b) through (c).

requirements, amendments must be submitted as soon as possible, but no later than 60 days from the effective date of the change to State law concerning advance directives.
(2) Prompt submittal of amendments is necessary—
(i) So that CMS can determine whether the plan continues to meet the requirements for approval; and
(ii) To ensure the availability of FFP in accordance with §430.20.

State Plan Requirements

The term "medical assistance" is defined at section 1905(a) of the Act, as "payment of all or part of the costs" on behalf of the eligible recipients of specified care and services which are outlined in almost thirty underlying subsections.[19] The services provided as medical assistance include at section 1905(a)(4)(C) "family planning services and supplies furnished (directly or under arrangements with others) to individuals of child-bearing age (including minors who can be considered to be sexually active) who are eligible under the State plan and who desire such services and supplies...."[20] Section 1903(b)(5) of the Act provides for Federal payment of 90 percent of the costs for family planning services in all States.[21] By definition "medical assistance" only pays for specifically identified covered items and services for eligible individuals. The Medicaid program does not pay for abortions not covered by the narrow Hyde amendment exceptions. Under a traditional State plan, the payment for covered services is made directly by the State to the individuals or entities that furnish the services.

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[19] Section 1905(a) of the Act.
[20] Family planning services would include services which are unrelated to abortion, including cervical Pap smears, HIV testing, treatment of sexually transmitted diseases, contraceptive pills and supplies. CMS Hearing Brief at 4.
[21] Section 1903(a) states that: "From the sums appropriated therefor, the Secretary (except as otherwise provided in this section) shall pay to each State which has a plan approved under this title, for each quarter, *** 5) an amount equal to 90 per centum of the sums expended during such quarter which are attributable to the offering, arranging, and furnishing (directly or on a contract basis) of family planning services and supplies..." *See also* 42 CFR 433.10(c)(1) ("(c) Special provisions. (1) Under section 1903(a)(5) of the Act, the Federal share of State expenditures for family planning services is 90 percent. ") and 433.15(b)(2) which addressing rates of FFP for administration of an approved state plan. (42 CFR 433.15 "(a) Basis. Section 1903(a) (2) through (5) and (7) of the Act provide for payments to States, on the basis of specified percentages, for part of their expenditures for administration of an approved State plan. (b) Activities and rates. ... (2) Administration of family planning services: 90 percent. (Section 1903(a)(5); 42 CFR 432.50(b)(5).")

Section 1902(a) sets out the requirements of a State plan for "medical assistance." Sections 1902(a)(4), 1902(a)(27). 1902(a)(57) and 1902(a)(58) provide certain rules regarding record-keeping and the disclosing and furnishing of information by all providers of services.[22] The regulation sets forth these State plan requirements at 42 CFR 431.107, which addresses "Required provider agreement."[23]

In addition, a State plan must meet the "free choice of provider" requirement at section 1902(a)(23), which states that:

> A State plan for medical assistance must—
>
> ****
>
> (23) provide that (A) any individual eligible for medical assistance (including drugs) may obtain such assistance from any institution, agency, community pharmacy, or person, qualified to perform the service or services required (including an organization which provides such services, or arranges for their availability, on a prepayment basis), 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 1915(b)(1)), 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 1905(a)(4)(C), except as provided in subsection (g), in section 1915, and in section 1932(a), except that this paragraph shall not apply in the case of Puerto Rico, the Virgin Islands, and Guam, and except that nothing in this

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[22] For example, section 1902(a)(27) provides for "agreements with every person or institution providing services under the State plan under which such person or institution agrees (A) to keep such records as are necessary fully to disclose the extent of the services provided to individuals receiving assistance under the State plan, and (B) to furnish the State agency or the Secretary with such information, regarding any payments claimed by such person or institution for providing services under the State plan, as the State agency or the Secretary may from time to time request."

[23] 42 CFR 431.107 provides that: "(a) Basis and purpose. This section sets forth State plan requirements, based on sections 1902(a)(4), 1902(a)(27), 1902(a)(57), and 1902(a)(58) of the Act, that relate to the keeping of records and the furnishing of information by all providers of services (including individual practitioners and groups of practitioners)." A State plan must provide for an agreement between the Medicaid agency and each provider or organization furnishing services under the plan in which the provider or organization agrees to certain maintain, disclose or furnish certain records.

> 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 or by a provider or supplier to which a moratorium under subsection (kk) (4) is applied during the period of the moratorium.[24]

The prohibition on limiting a recipient's "free choice of provider" for "family planning services" includes, *inter alia*, the prohibition on limiting such choice even for medical assistance provided under section 1915(b) managed care waivers (including waivers relating to case management systems).[25] Under section 1915(b) of the Act, a State may request that the Secretary waive the "free of choice of provider" requirement of section 1902(a)(23) in certain specified circumstances, but the law prohibits any restriction on a recipient's choice of a provider of family planning services.

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[24] Section 1902(a)(23), in 1987, read: "except as provided in section 1915 and except in the case of Puerto Rico, the Virgin Islands, and Guam, provide that any individual eligible for medical assistance (including drugs) may obtain such assistance from any institution, agency, community pharmacy or person, qualified to perform the services or services required (including an organization which provides such services, or arranges for their availability on a prepayment basis) who undertakes to provide him such services." Congress amended section 1902(a)(23) of the Act, when section 1902(p)(1) was added in 1987, to add the phrase "subsection (g) and in" before "section 1915." Section 4113(c)(1)(B) of the Omnibus Budget Reconciliation Act of 1987 (Pub. Law 100-203) added the language regarding the prohibition of restricting provider choice of family planning services under section 1905(a)(4)(C) of the Act under managed care type payment systems. Finally, section 4724(d)(2) of the Balanced Budget Act of 1997 (Pub. Law 105-33), (well after the establishment of section 1902(p)(1) of the Act), added the language concerning the State's authority to not make payment to entities or persons that had felony convictions, when determined to be inconsistent with the best interest of beneficiaries under the State plan.

[25] The Secretary explained in 1994 conforming technical changes that: "A. Freedom of Choice of Providers of Family Planning Services. **** Under section 1915(b) of the Act, a State may request that the Secretary waive the freedom of choice of provider requirement of section 1902(a)(23) in certain specified circumstances, but the law prohibits any restriction on a recipient's choice of a provider of family planning services. ....[W]e are revising §431.55(b) by adding a new paragraph (b)(2)(iv) to clarify that the prohibition against limiting a recipient's freedom of choice of family planning services applies to all section 1915(b) waivers (including waivers relating to case management systems)." *See* 59 Fed. Reg. 4597, 4598-99 (February 1, 1994)("Medicaid Program; Freedom of Choice Waiver; Conforming Changes").

Notably, in discussing the "free choice of provider" mandate, as established by the Social Security Amendments of 1967,[26] the Senate Report No. 90-744 explained that:

> Under the current provisions of law, there is no requirement on the State that recipients of medical assistance under a State title XIX program shall have freedom in their choice of medical institution or medical practitioner. In order to provide this freedom, a new provision is included in the law to require States to offer this choice. Effective July 1, 1969, States are required to permit the individual to obtain his medical care from any institution, agency, or person, qualified to perform the service or services, including an organization which provides such services or arranges for their availability on a prepayment plan. Under this provision, an individual is to have a choice from among qualified providers of service. Inasmuch as States may, under title XIX, *set certain standards for the provision of care*, and *may establish rates for payment*, it is possible that some providers of service may still not be willing or considered qualified to provide the services included in the State plan. *This provision does not obligate the State to pay the charges of the provider without reference to its schedule of charges, or its standards of care.*[27] (Emphasis added.)

Thus, consistent with the statutory provision, the regulation at 42 CFR 431.51,[28] titled "Free choice of provider", states:

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[26] Pub. Law 90-248.

[27] The Senate Report also noted that, States were to offer special consultation services to medical agencies to enable them to "qualify" for payment. ("(j) *Consultation to institutions providing medical care.* One of the problems which has been recognized in the administration of titles XVIII and XIX is the difficulty in certifying the eligibility of certain suppliers of medical service. For this reason, the committee has included in the bill a provision requiring the States to offer special consultation, effective July 1, 1969, to various medical agencies to enable them to qualify for payment under the law....")

[28] 42 CFR 431.51 was codified at 42 CFR 449.20 from 1975 until redesignation in 1977. *See* 42 Fed. Reg. 52,827 (Sept. 30, 1977). The "Free Choice of Providers of Medical Services" regulation was first promulgated at 45 CFR Part 249 at 35 Fed. Reg. 8732-01 (June 5, 1970) and stated: "§249.11 Free choice of providers of medical services: State plan requirement. A State plan for medical assistance under title XIX of the Social Security Act must provide that any individual eligible for medical assistance under the plan may obtain the services available under the plan from any institution, agency, pharmacy, or practitioner, including an organization which provides such services or arranges for their availability on a prepayment basis, which is qualified to perform such services. This provision does not prohibit the State agency from establishing the fees which will be paid to providers for furnishing medical and remedial care available under the plan or from setting reasonable standards relating to the

> (a) Statutory basis. This section is based on sections 1902(a)(23), 1902(e)(2), and 1915(a) and (b) and 1932(a)(3) of the Act.
> (1) Section 1902(a)(23) of the Act provides that recipients may obtain services from any qualified Medicaid provider that undertakes to provide the services to them.
> ****
> (b) State plan requirements. A State plan, except the plan for Puerto Rico, the Virgin Islands, or Guam, must provide as follows:
> (1) Except as provided under paragraph (c) of this section and part 438 of this chapter, a recipient may obtain Medicaid services from any institution, agency, pharmacy, person, or organization that is—
> (i) Qualified to furnish the services; and
> (ii) Willing to furnish them to that particular recipient.[[29]]
>
> This includes an organization that furnishes, or arranges for the furnishing of, Medicaid services on a prepayment basis.
> (2) A recipient enrolled in a primary care case-management system, a Medicaid MCO, or other similar entity will not be restricted in freedom of choice of providers of family planning services.

The regulation at 42 CFR 431.51, paragraph (c), adopted language similar to that used in the legislative history, when it states that:

> (c) Exceptions. Paragraph (b) of this section does not prohibit the agency from—
> (1) Establishing the fees it will pay providers for Medicaid services;
> (2) Setting reasonable standards relating to the qualifications of providers....[30]

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qualifications of providers *of such care*....." When the Medicaid regulation was reorganized at 43 Fed Reg. 45176 (September 29, 1978) with clarifying editorial changes with no policy changes "in the existing regulations", the words "of such care" were not retained.

[29] *See also* 56 Fed Reg. 8832 (March 1, 1991)("Medicare and Medicaid Programs; OBRA '87 Conforming Amendments")("These provisions required us to amend §§431.51 and 435.212. In §431.51(b)(1), we have added language to counteract a misunderstanding that has arisen in the past: freedom of choice does not obligate a Medicaid provider to furnish services to every recipient. Within specified limits, a recipient may seek to obtain services from any qualified provider, but the provider determines whether to furnish services to the particular recipient. This is consistent with the language of § 1902(a)(23) of the Act; "* * * who undertakes to provide him such services.")

[30] *See also* 44 Fed. Reg. 30382, 30383 (May 25, 1979)("Medicaid Program; Reimbursement for Eyeglasses and Hearing Aids" Proposed Rule) ("Section 1902(a)(23) of the Social Security Act requires Medicaid State plans to provide 'that any individual eligible for

Thus, the 42 CFR 431.51(c) exceptions explain that a State is not prohibited, under section 1902(a)(23), from "establishing the fees it will pay providers for Medicaid service" and "setting reasonable standards relating to the qualifications of providers" as established and set in conformity with the overall State plan requirements of Title XIX. A State's authority to establish the fees it will pay providers and to set reasonable qualifications are provided at various provisions of the Title XIX.[31]

Finally, a "Center for Medicaid, CHIP and Survey & Certification Informational Bulletin," dated June 1, 2011, repeated the longstanding Federal law regarding the Medicaid requirement of "Freedom of Choice" stating that:

> We have received some inquiries as to whether States may exclude certain providers from participating in Medicaid based on their scope of practice, as well as a proposed state plan amendment presenting the same question, and we thought a review of longstanding federal law would be helpful to States.

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medical assistance (including drugs) may 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.' The regulations at 42 CFR 431.51 essentially repeat the statutory requirement. Freedom of choice is a concept which exists for the benefit of recipients, not for the benefit of providers or suppliers."

[31]For example, section 1902(a)(30)(A), requires a State plan provide "such methods and procedures relating to the utilization of, and the payment for, care and services available under the plan... as may be necessary to safeguard against unnecessary utilization of such care and services and to assure that payments are consistent with efficiency, economy, and quality of care and 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." Generally, the Medicaid statute grants States the authority to define reasonable standards relating to qualifications for providers as it relates to fitness to practice. For example, section 1902(a)(9)(A) of the Act provides that the State (using the same State health agency Medicaid program as provided under section 1864(a) of the Act) is to set and maintain additional standards for the State Medicaid program; section 1902(a)(22) requires that State plans, *inter alia*, set forth the standards for public and private institutions in which Medicaid recipients may receive care; and section 1902(a)(33)(B) provides, *inter alia*, that the State agency shall be responsible for establishing a plan for review of the appropriateness and quality of care and services furnished to Medicaid recipients. The Secretary has retained certain "look behind" authority.

> States have authority to exclude providers from participating in Medicaid under certain circumstances, and indeed in some situations federal law requires exclusion. States are required, for example, to exclude providers that commit fraud or certain criminal acts. States are not, however, permitted to exclude providers from the program solely on the basis of the range of medical services they provide. Under federal law Medicaid beneficiaries may obtain medical services "from any institution, agency, community pharmacy, or person, qualified to perform the service or services required . . . who undertakes to provide him such services." (Section 1902(a)(23) of Title XIX of the Social Security Act (the Act)) This provision is often referred to as the "any willing provider" or "free choice of provider" provision.
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> Federal Medicaid funding of abortion services is not permitted under federal law except in extraordinary circumstances (in cases of rape, incest, or when the life of the woman would be in danger). At the same time, Medicaid programs may not exclude qualified health care providers—whether an individual provider, a physician group, an outpatient clinic, or a hospital—from providing services under the program because they separately provide abortion services (not funded by federal Medicaid dollars, consistent with the federal prohibition) as part of their scope of practice.[32]

General Medicaid Fraud and Abuse Provisions

Historically, there has been a series of Federal laws establishing the framework and funding for fraud and abuse oversight activities.[33] Generally, when Medicare and Medicaid were enacted in 1965, there were limited provisions in the law prohibiting, *inter alia*, the making of false statements to obtain reimbursement or to represent the condition or operation of a health care facility. Congress increased the penalties for such conduct in the Social Security Amendments of 1972,[34] making sure that the provisions would be in addition to, and not in lieu of, any other similar penalty provisions in State or Federal law.

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[32] "Center for Medicaid, CHIP and Survey & Certification Informational Bulletin", dated June 1, 2011.

[33] The following discussion is not intended to be, and is not, a full all inclusive review of all of the often statutorily revisited and numerous Medicaid fraud and abuse provisions, but rather a more narrow historical review of certain relevant State-based Medicaid fraud and abuse authorities as they may relate to the issues raised herein.

[34] Pub. Law No. 92-603.

The enactment of section 17 of the Medicare and Medicaid Anti-Fraud and Abuse Amendments of 1977[35] authorized the establishment of State Medicaid Fraud Control Units in each State and added a new paragraph at section 1903(q).[36] In authorizing and funding the State fraud units, section 1903(q) provided that the specific function of the entity is conducting a statewide program for the investigation and prosecution of violations of "all applicable State laws regarding any and all aspects of fraud *in connection* with any aspect of the provision of medical assistance and the activities of providers of such assistance *under the State plan under this title....*" The entity also is to have procedures, *inter alia*, "for reviewing complaints of abuse or neglect" of patients in health care facilities which receive payments under the State plan under this title. These State Medicaid Fraud Control Unit procedures, and the continuing existing State obligations relating to Medicaid-related and defined fraud and abuse oversight, were initial promulgated at 42 CFR 455.1, *et seq.*.[37]

As early as 1980, the Secretary proposed further rules to allow States to exclude providers, reasoning, *inter alia*, that if States had greater regulatory authority to take sanctions appropriate to uncover Medicaid related fraud and abuse offenses, the dollar recovery and sanctions imposed would have been substantially greater.[38] Therefore, the efficient

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[35] Pub. Law No. 95-142.

[36] *See also* S. Rep. 95-453 ("Medicare-Medicaid Anti-fraud and Abuse Amendments of 1997, Report of the Committee on Finance, US Senate, on S 143 (95th Cong. 1st Sess.)(Sept. 1977) at 36.)

[37] The State of Indiana's "Indiana State Medicaid Fraud Unit" (IMFU) is authorized under Indiana Code (IC) 4-6-10, "Chapter 10" "State Medicaid Fraud Control Unit" "IC 4-6-10-1 Establishment; certification Sec. 1. The attorney general shall: (1) establish a state [M]edicaid fraud control unit that meets the standards prescribed by 42 U.S.C. 1396b(q); and (2) apply to the secretary of the federal Department of Health and Human Services for certification of the unit under 42 U.S.C. 1396b(q)[1903(q)]. IC 4-6-10-1.5. "Authority to investigate." Sec. 1.5. The state Medicaid fraud control unit has the authority to: (1) investigate, in accordance with federal law (42 U.S.C. 1396 et seq.): (A) Medicaid fraud; (B) misappropriation of a Medicaid patient's private funds; (C) abuse of Medicaid patients; and (D) neglect of Medicaid patients; and (2) investigate, in accordance with federal law (42 U.S.C. 1396 et seq.) and as allowed under 42 U.S.C. 1396b(q)[1903(q)](4)(A)(ii), abuse or neglect of patients in board and care facilities."

[38] 45 Fed. Reg. 83772 (Dec. 18, 1980)("Medical Assistance Program Title XIX Administrative Sanctions")(Proposed rule)("The proposed regulation would require State Medicaid agencies to suspend from program reimbursement all practitioners who are convicted of offenses related to their participation in the Medicaid program and to exclude from Medicaid program reimbursement providers who otherwise defraud or abuse the Medicaid program. The proposed regulation also revises State Medicaid requirements with respect to the detection and investigation of Medicaid fraud and abuse. This revision would further clarify State Medicaid agency responsibilities for the control of Medicaid fraud and

administration of the Medicaid program dictated that State Medicaid agencies establish and maintain processes to administer sanctions when appropriate.[39] Under the Medicaid program integrity provisions of 42 CFR 455.1, *et seq*., the term "fraud" was defined as "an intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to himself or some other person. It includes any act that constitutes fraud under applicable State law" as perpetrated within the

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abuse and strengthen the regulatory requirements so that States can adequately meet their responsibilities. The intent of this proposed regulation is to prevent or discourage those practices which increase the cost of the Medicaid program without benefiting Medicaid recipients.")("Major Provisions and Policy Issues *1. Exclusion of Medicaid Providers.* **** These provisions are the same as Medicare uses when considering an exclusion under section 1862(d)(1),[*] and are intended to more closely align the exclusion processes in the two programs.") These requirements were eventually set forth at 42 CFR 455.203 (1983) "Exclusion of Medicaid providers for fraud and abuse" at 48 Fed Reg. 3742 (Jan. 27, 1983) ("Medicare and Medicaid Programs; Suspension of Health Care Professionals for Conviction of Program-Related Crimes)(Final rule with comment period); 46 Fed. Reg. 47996 (September 30, 1981)("Medicaid Program; Reductions in Payments to the States") (Interim Final Rule with Comment Period.); 45 Fed. Reg. 83772 (Dec. 18, 1980)("Medical Assistance Program Title XIX Administrative Sanctions")(Proposed rule).
[*Section 1862(d)(1) was repealed by section 8(c) of the MMPPPA of 1987, which put in place, *inter alia,* similar exclusion provisions at sections 1128, *et seq*.]

[39] *See e.g.* 42 CFR 455.203 (1983) ("Exclusion of Medicaid providers for fraud and abuse. (a) Basis for exclusion. The agency must have administrative procedures which enable the agency to exclude from Medicaid reimbursement a provider who it determines has: (a)(1) Knowingly and willfully made or caused to be made any false statement or misrepresentation of material fact in claiming, or use in determining the right to, payment *under Medicaid*; (a)(2) *Furnished or ordered services under Medicaid* that are substantially in excess of the recipient's needs or that fail to meet professionally recognized standards for health care; or (a)(3) Submitted or caused *to be submitted to the Medicaid program bills* or requests for payment containing charges or costs that are substantially in excess of customary charges or costs. However, the agency must not impose an exclusion under this section if it finds the excess charges are justified by unusual circumstances or medical complications requiring additional time, effort, or expense in localities in which it is accepted medical practice to make an extra charge in such case. (b) Reports to be considered. The agency may base its determination that services were excessive or of unacceptable quality on reports, including sanction reports, from any of the following sources: (b)(1) The PSRO for the area served by the provider; (b)(2) State or local licensing or certification authorities; (b)(3) Peer review committees of fiscal agents or contractors; (b)(4) State or local professional societies; or (b)(5) Other sources deemed appropriate by the Medicaid agency or [CMS].")

context of providing services under the Medicaid program.[40] In addition, under that same Part 455 provision the term "abuse" was defined as meaning "provider practices that are inconsistent with sound fiscal, business, or medical practices, and result in an unnecessary cost to the Medicaid program, or in reimbursement for services that are not medically necessary or that fail to meet professionally recognized standards for health care...."[41] Thus, the term "abuse" included in its definition, not only provider practices relating to Medicaid billing and financial record keeping, but practices relating to standard of care provided Medicaid recipients. State Medicaid programs were authorized to look, *inter alia*, to State and professional licensing bodies in making determinations on excessive or substandard quality of care practices.

In 1983, the Secretary of the Department of Health and Human Services (HHS) transferred the authorities for controlling fraud and abuse in the Department's health care financing programs from CMS (at that time referred to as the Health Care Financing Administration or HCFA) to the Office of Inspector General (OIG).[42] There were a number of other statutory

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[40] Early in the Medicaid program, for purposes of the "Medicaid Agency Fraud Detection and Investigation Program" the definition of fraud relating to Medicaid activities was to be "determined in accordance with State law." 42 CFR 455.11 (1978). This was later amended in 1983 as noted above at 42 CFR 455.2. *See* 48 Fed Reg. 3742 (Jan. 27, 1983)("Medicare and Medicaid Programs; Suspension of Health Care Professionals for Conviction of Program-Related Crimes; Exclusion of Medicaid Providers for Fraud and Abuse")(Final rule with comment period); 46 Fed. Reg. 47996 (September 30, 1981)(Interim Final Rule with Comment Period)("Medicaid Program; Reductions in Payments to the States" "Medical Assistance Program Title XIX Administrative Sanctions"); 45 Fed. Reg. 83772 (Dec. 18, 1980)(Proposed rule).

[41] Early in the Medicaid program, "abuse" was not defined, however by 1983, the regulations at 42 CFR 455.2 set forth the definition above. *See, e.g.*, 48 Fed Reg. 3742 (Jan. 27, 1983)("Medicare and Medicaid Programs; Suspension of Health Care Professionals for Conviction of Program-Related Crimes; Exclusion of Medicaid Providers for Fraud and Abuse").

[42] 48 Fed. Reg. 21662 (May 13, 1983); 48 Fed. Reg. 45306 (Oct 4, 1983); 49 Fed. Reg. 29849 (July 24, 1984). This delegation of authority provided that the OIG would make the necessary determinations and effectuate the appropriate sanctions under sections 1128, 1156(b), 1160(b) (as set forth prior to Pub. L. 97-248), 1862(d)(1) and (2), and 1866(b)(2)(D), (E) and (F) of the Social Security Act, and take action under section 1866(c)(1) with respect to determinations taken under section 1866(b)(2)(D), (E) or (F) of the Act. To reflect this transfer of fraud and abuse authority to the OIG, the final regulations, "The Medicare and Medicaid Fraud and Abuse Technical Amendments", were published on September 13, 1985. 51 Fed. Reg. at 34764. 50 Fed. Reg. 37370 (Sept. 13, 1985)(including a series of technical changes to reflect changes in responsibility for fraud and abuse determinations.)

authorities relating to program fraud and abuse under Medicaid that were retained by CMS.[43] In 1986, all HHS OIG authorities, that were contained in portions of 45 CFR including Part 455, were established in a new 42 CFR Chapter V including the previous 1983 transfer of the fraud and abuse oversight responsibilities.[44] Notably, CMS continued to retain, *inter alia*, the delegated authorities for enforcing State plan requirements as set forth at 42 CFR Part 455, *et seq.*,[45] and specific regulations were also included in Parts 1000, *et seq.*,[46] for the

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[43] For example, CMS continued to retain specific responsibility for enforcing State plan requirements, even though some of these requirements pertain to State obligations in enforcing OIG sanction authorities. The CMS-delegated authorities, at that time, in 1986 included sections 1126, 1902(a)(4)(A), 1902(a)(30), 1902(a)(39), 1903(i)(2) and 1903(n) (some of which may since been amended, etc.).

[44] 51 Fed. Reg. 34764 (Sept. 30, 1986)("Medicare and Medicaid Programs; Establishment of Chapter V for OIG Regulations")(Final rule).

[45] 51 Fed. Reg. 34786 (Sept. 30, 1986)("Medicare and Medicaid Programs; Program Integrity")(Final rule). ("§455.1 Basis and scope. This part sets forth requirements for a State fraud detection and investigation program, and for disclosure of information on ownership and control. (a) Under the authority of sections 1902(a)(4), 1903(i)(2), and 1909 of the Social Security Act, Subpart A provides State plan requirements for the identification, investigation, and referral of suspected fraud and abuse cases. In addition, the subpart requires that the State (1) report fraud and abuse information to the Department and (2) have a method to verify whether services reimbursed by Medicaid were actually furnished to recipients. (b) Subpart B implements sections 1124, 1126, 1902(a)(36), 1903(i)(2), and 1903(n) of the Act. It requires that providers and fiscal agents must agree to disclose ownership and control information to the Medicaid State agency.")

[46] *See e.g.*, "42 CFR 1002.1 Basis and purpose.(a) This part sets forth requirements for the prevention of fraud and abuse in the Medicaid program and implements specific statutory provisions aimed at protecting the integrity of the program. (b) Subpart B is based on sections 1126, 1128, 1902(a)(4)(A), 1902(a)(30), 1902(a)(39) and 1903(i)(2) of the Social Security Act. It requires Medicaid agencies to—(1) Have the ability to exclude from program reimbursement any provider that defrauds or abuses the Medicaid or Medicare program and (2) Suspends any individual receiving reimbursement under the Medicaid program who has been convicted of a crime related to delivery of medical care or services under the Medicare, Medicaid, or social services programs. (c) Subpart C implements sections 1903(a)(6), 1903(b)(3), and 1903(q) of the Social Security Act, and prescribes requirements for the establishment and operation of State Medicaid fraud control units. It also details conditions that must be met in order for costs of the fraud control units to quality for 90 percent Federal financial participation (FFP)."

"§1002.200 State plan requirement. The plan must provide that the requirements of this subpart are met. However, the provisions of these regulations are minimum requirements. The agency may impose broader sanctions if it has the authority to do so under State law."

convenience of developing a comprehensive regulatory package of the Department's fraud and abuse related provisions in one location.[47] The definition of fraud remained unchanged.

At that time, exclusions imposed by the Office of Inspector General (OIG) were based on the authorities set forth in sections 1128, 1156 and 1892 of the Social Security Act. In imposing these exclusions, the Secretary's primary objective and obligation was to protect the programs and their beneficiaries from unfit health care providers, individuals and businesses whose behavior has demonstrated that they pose a risk to program beneficiaries or to the integrity of the Medicare and State health care programs.

In 1987, the OIG's civil administrative sanction authorities were significantly revised and expanded by the Medicare and Medicaid Patient and Program Protection Act (MMPPPA).[48] Congress enacted MMPPPA "to improve the ability of the [Department] to protect the Medicare and Medicaid programs for fraud and abuse, and to protect the beneficiaries of these programs from incompetent practitioners and from inappropriate and inadequate care."[49] MMPPPA authorized both mandatory and discretionary program exclusions intended to protect the integrity of the Medicare and State health care programs, as well as beneficiaries. The MMPPPA of 1987 recodified certain existing authority, and expanded other new authority, that provided for the Secretary to exclude various individuals and entities from receiving payment for services that would otherwise be reimbursable under the

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51 Fed. Reg. 34764. (Sept. 30, 1986)("Medicare and Medicaid Programs; Establishment of Chapter V for OIG Regulations").

[47] 51 Fed. Reg. 34764. (Sept. 30, 1986)("Medicare and Medicaid Programs; Establishment of Chapter V for OIG Regulations"). Concurrently, in Part 455 (which deals with program integrity in Medicaid), the Secretary removed Subparts C and D; revised §455.1 (Basis and scope) to limit the description of the scope to those aspects that remain in Part 455 because they continued to be CMS' responsibility; and added a new §455.3. 51 Fed. Reg. 34786 (Sept. 30, 1986)("Medicare and Medicaid Programs; Program Integrity").

[48] Pub. Law 100-93.

[49] *See* S. Rep. 100-109 at 1-2. ("The Committee on Finance, to which was referred the bill (S. 661) to amend titles XI, XVIII, and XIX of the Social Security Act to protect beneficiaries under the health care programs of that Act from unfit health care practitioners, and otherwise to improve the antifraud provisions relating to those programs, having considered the same, reports favorably thereon with an amendment in the nature of a substitute to the text, and recommends that the bill as amended do pass. I. PURPOSE AND SUMMARY. The basic purpose of the Committee bill is to improve the ability of the Secretary and the Inspector General of the Department of Health and Human Services to protect Medicare, Medicaid, Maternal and Child Health Services Block Grant, and Title XX Social Services Block Grant programs from fraud and abuse, and to protect the beneficiaries of those programs from incompetent practitioners and from inappropriate or inadequate care.")

Medicare and Medicaid and other Federal health care programs. In particular, the MMPPPA consolidated many of the Secretary's pre-existing authority in section 1128 of the Social Security Act and added significant new grounds for exclusions under those authorities.[50]

In addition, section 7 of the MMPPPA of 1987, added section 1902(p) of the Act, which provides that:

> (1) 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,[[51]] 1128A,[[52]] or 1866(b)(2).[[53]]

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[50] 57 Fed. Reg. 3298 (Jan. 29, 1992)("Health Care Programs: Fraud and Abuse Amendments to OIG Exclusions and CMP Authority Resulting from P.L. 100-93.")

[51] Section 1128 refers to "Exclusion of certain individuals and entities from participation in Medicare and State health care programs" and refers to mandatory exclusions (conviction of program-related crimes; conviction relating to patient abuse; felony conviction relating to health care fraud; felony conviction relating to controlled substance) and permissive exclusions (conviction relating to fraud; conviction relating to obstruction of an investigation or audit; misdemeanor conviction relating to controlled substance; health care License revocation or suspension, exclusion or suspension under federal or state health care program; claims for excessive charges or unnecessary services and failure of certain organizations to furnish medically necessary services; fraud, kickbacks, and other prohibited activities; failure to disclose required information; failure to supply requested information on subcontractors and suppliers; failure to supply payment information; failure to grant immediate access; failure to take corrective action; default on health education loan or scholarship obligations; individuals controlling a sanctioned entity; making false statements or misrepresentation of material facts.)

[52] Section 1128B refers to criminal penalties for acts involving Federal health care programs.

[53] Section 1866(b)(2) refers to enrollments and agreements to participate and explains that: "(2) The Secretary may refuse to enter into an agreement under this section or, upon such reasonable notice to the provider and the public as may be specified in regulations, may refuse to renew or may terminate such an agreement after the Secretary—(A) has determined that the provider fails to comply substantially with the provisions of the agreement, with the provisions of this title and regulations thereunder, or with a corrective action required under section 1886(f)(2)(B), (B) has determined that the provider fails substantially to meet the applicable provisions of section 1861, (C) has excluded the provider from participation in a program under this title pursuant to section 1128 or section 1128A, or (D) has ascertained that the provider has been convicted of a felony under Federal or State law for an offense which the Secretary determines is detrimental to the best interests of the program or program beneficiaries. (3) A termination of an agreement or a

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(3) As used in this subsection, the term "exclude" includes the refusal to enter into or renew a participation agreement or the termination of such an agreement.

Thus, in accordance with section 1902(p)(1) of the Act, the States have the authority to initiate exclusions of individuals or entities who could be excluded from Medicare by the Federal government under sections 1128, 1128A or 1866(b)(2) of the Act. The Department is authorized to require State agencies to develop mechanisms for implementing and terminating exclusions imposed under these authorities.[54] These provisions also clarify, by statute, that the Secretary may require States to adopt certain administrative procedures when they impose exclusions at the direction of the Secretary under the Secretary's exclusion or civil money penalty authorities.[55]

Furthermore, when an individual or entity has been excluded, suspended, or otherwise sanctioned by a State Medicaid agency, the OIG is authorized to exclude that individual or entity from Medicare and all State health care programs in accordance with section 1128(b)(5) of the Act, that is, to "piggyback" onto the State-initiated exclusion an additional nationwide exclusion from Medicare and all State health care programs. Thus, the OIG's exclusion is based upon a State agency's determination that a provider is unfit to participate in their State Medicaid program. This provision was to prevent a State excluded provider from moving to another State to continue practice.[56]

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refusal to renew an agreement under this subsection shall become effective on the same date and in the same manner as an exclusion from participation under the programs under this title becomes effective under section 1128(c)."

[54] Under section 1902(a)(39) of the Act, which sets forth the requirements for State Medicaid plans, the State programs are also obligated to "provide that the State agency shall exclude any specified individual or entity from participation * * * when required to do so pursuant to section 1128 or section 1128A." In addition, section 1902(a)(4) of the Act states that plans must provide "such methods of administration * * * as are found by the Secretary to be necessary for the proper and efficient operation of the plan."

[55] 57 Fed. Reg. 3298, 3322 (Jan. 29, 1992)("Health Care Programs: Fraud and Abuse; Amendments to OIG Exclusion and CMP Authorities Resulting From Public Law 100-93").

[56] *See also* S. Rep. 100-109 at 3-4 explained that: " The GAO report found that Medicare and Medicaid patients are being treated in some States by health care practitioners whose licenses were revoked or suspended by another State's licensing board because they did not meet minimum professional standards.... Such practitioners are able to treat Medicare and Medicaid patients because HHS does not have the authority to exclude them from these programs in all States based on licensing board findings and sanctions in one State. ...."

Section 1902(p) of the Act was implemented in the regulations at 42 CFR Part 1002, *et seq.* Since the new requirements of the MMPPPA of 1987 were incorporated into 42 Part 1001 (which would require State health care programs, including Medicaid, to exclude those whom the OIG had excluded under Medicare),[57] the proposed new Part 1002 was designed to set forth provisions pertaining only to State agency-initiated exclusions. These regulations required, *inter alia*, that State Medicaid agencies have similar due process procedures in place for initiating exclusions of individuals and entities that could be excluded from Medicare under section 1128, 1128A or 1866(b)(2) of the Act.[58] In implementing section 1902(p), the regulations at 42 CFR 1002.1 and 1002.2 read in 1992 and going forward, that:

> 1002.1 *Scope and purpose*. The regulations in this part specify certain bases upon which individuals and entities may, or in some cases must, be excluded from participation in the Medicaid program. These regulations specifically address the authority of State agencies to exclude on their own initiative, regardless of whether the OIG has excluded an individual or entity under part 1001 of this chapter. These regulations also delineate the States' obligation to inform the OIG of certain Medicaid-related convictions.
> 1002.2 *General authority*. (a) In addition to any other authority it may have, a State may exclude an individual or entity from participation in the Medicaid program for any reason for which the Secretary could exclude that individual or entity from participation in the Medicare program [and other Federal health care programs[59]] under sections 1128, 1128A or 1866(b)(2) of the Social Security Act.

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[57] *See, e.g.,* 42 CFR 1001.1 ("Scope and purpose. (a) The regulations in this part specify certain bases upon which individuals and entities may, or in some cases must, be excluded from participation in Medicare, Medicaid and all other Federal health care programs. They also state the effect of exclusion, the factors that will be considered in determining the length of any exclusion, the provisions governing notices of exclusions, and the process by which an excluded individual or entity may seek reinstatement into the programs.")

[58] 57 Fed. Reg. 3298, 3300 (Jan. 29, 1992)(Final rule)("Health Care Programs: Fraud and Abuse; Amendments to OIG Exclusion and CMP Authorities Resulting From Public Law 100-93") 55 Fed. Reg. 12205 (April 2, 1990)(Proposed Rule)("Health Care Programs: Fraud and Abuse; Amendments to OIG Exclusion and CMP Authorities Resulting From Public Law 100-93."); 56 Fed. Reg. 33403, 33404 (July 22, 1991)(Implementing the MMPPA section 7 with respect to State obligations regarding HMO contracts etc.), ("Medicare and State Health Care Programs: Fraud and Abuse; Civil Monetary Penalties and Intermediate Sanctions for Certain Violations by Health Maintenance Organizations and Competitive Medical Plans")

[59] In 1998, to ensure that the OIG's program exclusion authority was consistent with other sanction authorities set forth in sections 1128A and 1128B, section 4331(c) of BBA specifically amended sections 1128(a) and (b) of the Act to provide that the scope of an OIG

> (b) Nothing contained in this part should be construed to limiting State's own authority to exclude an individual or entity from Medicaid for any reason or period authorized by State law.[60]

The OIG also took over responsibility for oversight activities for the State Medicaid fraud control units[61] to investigate and prosecute fraud and abuse relating to its State Medicaid program.[62] Thus, there has been a narrowly prescribed State component from early in the Medicaid program with respect to Medicaid related and defined "fraud" and "abuse" oversight matters.

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exclusion extends beyond Medicare and the State health care programs to all Federal health care programs, as defined in section 1128B(f) of the Act, and to enable the OIG to impose exclusions from all Federal health care programs directly. The term "Federal health care program" was added to 42 CFR 1002.2(a)63 Fed. Reg. 46736 (Sept. 2, 1998)("Health Care Programs: Fraud and Abuse; Revised OIG Sanction Authorities Resulting From Public Law 105-33")

[60] 57 Fed. Reg. 3298, 3322 (Jan. 29, 1992)("Health Care Programs: Fraud and Abuse; Amendments to OIG Exclusion and CMP Authorities Resulting From Public Law 100-93"). The OIG rejected a proposal that the language in 42 CFR 1002.2 should be changed to "Nothing contained in this part should be construed to limit a State's own authority to exclude an individual or entity from Medicaid *for cause* for any period authorized by State law." *Id.* at 3322-23. Moreover, in addition to the OIG authorities involved in the foregoing OIG rulemaking, CMS retains authority over State plan requirements and the Medicaid program, generally.

[61] *See e.g.* 73 Fed. Reg. 12455-02 (March 7, 2008) ("General Office of the Secretary; Statement of Organization, Functions, and Delegations of Authority")

[62] The corresponding existing regulations were eventually implemented in a new 42 CFR Part 1007, *et seq* 57 Fed Reg. 3355, (Jan. 29, 1992) April 2, 1990. The language at section 1007 mostly mirrors the language at former 42 CFR Part 455. *See e.g.* 42 CFR 1007.3 Scope and purpose. This part implements sections 1903(a)(6), 1903(b)(3), and 1903(q) of the Social Security Act, as amended by the Medicare-Medicaid Anti-Fraud and Abuse Amendments (Pub. L. 95-142). ....1007.11 Duties and responsibilities of the unit. (a) The unit will conduct a Statewide program for investigating and prosecuting (or referring for prosecution) violations of all applicable State laws pertaining to fraud in the administration of the Medicaid program, the provision of medical assistance, or the activities of providers of medical assistance under the State Medicaid plan. (b) (1) The unit will also review complaints alleging abuse or neglect of patients in health care facilities receiving payments under the State Medicaid plan and may review complaints of the misappropriation of patient's private funds in such facilities."

Finding and Conclusions

The State challenged the legal basis for the CMS Presiding Officer's interpretation of the term "qualified" in section 1902(a)(23) of the Act as too limited. The State argued that the SPA 11-011 was adding a new valid provider "qualification." The State pointed to certain other approved State plans, which it claimed recognizes that there can be an allowable "incidental" reduction of provider choice due to valid, State-determined, provider "qualifications." The State argued that any lack of provider choice caused by the SPA is an allowable "incidental" consequence of the implementation of SPA 11-011, because it represents a valid provider "qualification." The State also claimed that the Presiding Officer ignored the language setting forth both the preservation and expansion of the State's authority to exclude a provider in section 1902(p)(1) of the Act and objected to the Presiding Officer's dismissal of the supporting legislative history of section 1902(p)(1) of the Act. The limited view of the State's authority, adopted by the Presiding Officer, to exclude providers under section 1902(p)(1) of the Act and the regulations at 42 CFR Part 1002 was only showing a policy preference, as this view was not supported by the text. In addition, regarding the individual nature of provider exclusions, the exclusion under SPA 11-011 would in fact allow for "singular" and "provider-focused" exclusionary adjudications. In sum, the State contended it had the power to "exclude", as a "qualification" for Medicaid participation, a class of providers because it determined that scope of the providers' noncovered practice was contrary to the State's policy interest.[63]

Section 1902(a)(23) of the Act

The Administrator finds that, section 1902(a)(23) of the Act and the regulation at 42 CFR 431.51 require that the Medicaid State plans must allow Medicaid recipients the free choice

[63] The State maintains that the State interest arises because allegedly Medicaid funds are used to indirectly subsidize/cross-subsidize the cost of abortion services in Medicaid family planning service providers that provide such services in their non-covered scope of practice. *See, e.g.*, Stipulation of Evidence" at para.11; State Post-Hearing Memorandum at 8 ("SPA 11-011 advances the public policy of the State that the taxpayer money not be used to subsidize abortions even indirectly.") *See also* Presiding Hearing Officer's recommended decision at pp 8-9 regarding the clarification that the SPA is to prevent both indirect subsidies and cross-subsidies. In response to this particular claim, CMS maintained at the hearing and in extensive briefing, that, *inter alia*, the State's definition of indirect subsidization/cross-subsidization was so broad as to give it no meaning other than "money once received is fungible." CMS pointed, as an example, to the State's witness who testified that: "as participants in a joint economy, we all indirectly subsidize each other." Transcript of Oral Hearing at 92-93; "[T]he fact we are all in one giant economy together means that indirect subsidies occur all over the place." *Id.* at 132. *See also* CMS Post-Hearing Brief at 20-28; CMS Hearing Brief at 25-28, further rebutting this premise.

of providers that are qualified and willing to perform the service or services.[64] The Administrator agrees that States have the authority to design "reasonable" provider "qualifications" to ensure that Medicaid-participating providers are able to perform services competently and in a manner that protects the fiscal integrity of the Medicaid program and that States may assert their rate-setting authority in conformity with the State plan requirements. However, States are not free to ascribe any meaning to the statutory term "qualified," especially one that would effectively eliminate the ability of Medicaid individuals to receive services from specific providers for reasons not related to their "qualification" to provide such services, as the term "qualification" is used generally and in the Medicaid program.

The Administrator finds that the term "qualified" as used in section 1902(a)(23) of the Act unambiguously relates to a provider's fitness to perform the patient required medical services. The statute provides that Medicaid beneficiaries "may obtain [medical] assistance from any institution, agency ... or person ... qualified to perform the service or services required." As conventionally used, "qualified" means "fitted (as by training or experience) for a given purpose or condition" (i.e., "competent")."[65] The *Black's Law Dictionary* (9th ed. 2009), describes "qualified" as one "[p]ossessing the necessary qualifications; capable or competent." To be "qualified" in any relevant sense is to be capable of performing the needed medical services in a professional competent, safe, and legal manner.[66] "Qualified" not only by definition, but in this context, is inextricably linked to the fitness or competency to "perform the service or services."[67]

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[64] As the court in *O'Bannon v. Town Court Nursing Center*, 447 U.S. 773, 785 (1980), recognized, section 1902(a)(23) of the Act gives Medicaid recipients "the right to choose among a range of qualified providers, without government interference."

[65] See "Qualified" definition Merriam-Webster's Dictionary, http://www.merriam-webster.com/dictionary/qualified

[66] The State did not further challenge the disapproval, or the recommended decision, under the *Pennhurst* "clear statement rule." The Administrator agrees with the Presiding Officer's analysis of the inapplicability of "*Pennhurst*", especially in light of the unambiguous use of the phrase "qualified to perform the service or services" and in light of the fact that the Legislative Services Agency clearly understood the common understanding of the term "qualified" in discussing the effects of HEA 1210. *See also* as herein incorporated the CMS Post-Hearing Brief at 16-20, discussion on *Pennhurst.*

[67] *See also* Presiding Officer's discussion that "a provider's qualifications are based on the actual 'perform[ance of] the service or services required." Recommended Decision at 19. In addition, other examples of the Secretary's consistent use of the word "qualified" or "qualification" as understood in the context of the standard of care or fitness to perform the services, under the Medicaid program, are at: 58 Fed Reg. 53481, 53482 ("Medicaid Program; Case Management")(Oct. 15, 1993) (Discussing provider "qualifications for case management services" stating that; "Because the Act does not set any minimum standards

The unambiguous meaning of the term "qualified" as used in this manner is also consistent with the legislative history of the Social Security Amendments of 1967, which established the "free choice of provider" requirement and specifically linked a provider's qualifications, as that term is used in section 1902(a)(23), to the "standard of care." The Senate Report stated that: "Inasmuch as States may, under title XIX, *set certain standards for the provision of care*, and *may establish rates for* payment, it is possible that some providers of service may still not be willing or *considered qualified* to provide the services included in the State plan. This provision does not obligate the State to pay the charges of the provider without reference to its schedule of charges, *or its standards of care*."[68]

In this case, the State does not contend that SPA 11-011 would exclude providers from participation in the Medicaid program on the ground that they are "unqualified" in the conventional use of that term. Instead, the State asserts that States are free to exclude providers on the basis of a scope of practice, of which a State may disapprove, simply by calling the required nonperformance of the disapproved practice a "qualification" of participation in Medicaid. The State, in arguing in support of the SPA, maintained that the State's authority to set "qualifications" includes the authority to establish provider-eligibility criteria based on a perceived legitimate State interest. However, such an interpretation, to allow States the freedom to set any qualifications, not related to the provider's fitness to treat Medicaid patients, would allow States to abrogate the "free choice of provider" requirement through the characterization of a State created exclusionary rule as a "qualification."

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for the provision of case management services, we are proposing to give States flexibility to establish reasonable qualifications for providers to ensure that providers are capable of providing services of acceptable quality, consistent with 42 CFR 431.51(c)(2), which allows States to set reasonable standards relating to the qualifications of providers.... States may limit participating providers in the program, but only through development of reasonable provider qualifications related to an entity's capacity to furnish case management services of adequate quality."); 73 Fed. Reg. 32088, 32095 (June 5, 2008)("Medicare and Medicaid Programs: Hospice Conditions of Participation") ("With regard to who is qualified to furnish homemaker services on behalf of a hospice, we proposed in §418.76(j) that a homemaker must have either completed home health aide training requirements or must have successfully completed a hospice's orientation addressing the needs and concerns of patients and families coping with a terminal illness.")

[68] In addition, the regulation at 42 CFR 431.51(c), promulgating the "free choice of provider" requirement explains that a State is not prohibited by this provision from "setting reasonable standards" relating to the "qualification" of a provider. As the limiting term "reasonable" in the regulation suggests, a State's authority to determine a provider's qualifications must be keyed to the 'permissible variations on the ordinary concept' of what it means to be 'qualified' in this context." *Planned Parenthood, Inc. v. Commissioner of the Indiana State Department of Health,* 699 F.3d 962 (7th Cir. Oct. 23, 2012).

Further, such an interpretation, that a State may choose to set any qualification as long as it is related to a perceived State interest, would nullify and make redundant and unnecessary the last part of section 1902(a)(23). That paragraph granted to the State the authority to *not* provide medical assistance for services furnished by a "provider convicted of a felony offense that the State determines is inconsistent with the best interest of beneficiaries under the State plan." If the Congress had intended that States have unrestricted ability to set "qualifications" for providers, such a provision in section 1902(a)(23) would not have been necessary.[69]

The State also attempts to link the SPA 11-011 to allegations that SPA 11-011 seeks to prevent indirect subsidizing of the providers' noncovered scope of practice and, thus, is related to reasonable standards of "billing practices." But a "reasonable standard" for billing practice "qualifications" would be linked to standards requiring that providers have in place the ability to bill correctly and accurately and properly document its billings. In contrast, the ability or fitness of the class of providers affected in this SPA to properly and accurately bill or meet recordkeeping requirements[70] in accordance with Medicaid rules have not been alleged or demonstrated as the reason for the SPA 11-011.[71]

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[69] Section 4724(d)(2) of the Balanced Budget Act of 1997, effective August 5, 1997 (and after the establishment of section 1902(p)(1) of the Act), amended paragraph (a)(23) of section 1902(a)(23) by inserting the language concerning felony convictions. The legislative history is not very expansive concerning this provision, however, section 4302 of the Balanced Budget Act of 1997, also concurrently amended section 1866(b)(2) to add new subparagraph using almost identical language concerning the authority of the Secretary to not entered into an agreement when a "provider has been convicted of a felony under Federal or State law for an offense which the Secretary determines is detrimental to the best interests of the program or program beneficiaries." Notably, the report explained that: "*Reason for change*. This is an important measure that will help to protect beneficiaries from potential harm. At the same time, however, the Committee recognizes that this recommendation could be read to provide broad authority to the Secretary. Therefore, it is the intent of the Committee that the Secretary exercise considerable discretion in utilizing this authority and weigh extremely carefully any decision to refuse to enter into an agreement, or to non-renew or terminate an agreement *only where there is clear evidence that beneficiaries will be harmed by entering into a relationship or renewing a relationship with a provider, physician or supplier.*" (Emphasis added.) H.R. Conf. Rep. 105-217.

[70] The State also does not explicitly tie its proposed SPA to any of the participation requirements explicitly listed under 42 CFR 431.107, pursuant to which it had submitted the SPA. *See infra* pp 2-3.

[71] *See also* CMS Brief at 26. The State concedes this point at State's Prehearing Brief at 6 ("This is true of course and entirely beside the point. The indirect subsidy issue has nothing to do with the legality of accounting practices and everything to do with the impossibility of

In addition, the State refers to violations of Codes of Professional Conduct, due to the commingling of funds, as examples of "qualifications." But those circumstances, *inter alia*, involve a breach of trust, when a fiduciary commingles funds held in trust for a client with the fiduciaries' own funds, raising a host of issues (breach of fiduciary duties, embezzlement, bankruptcy, etc.) not analogous to the situation presented here. The funds at issue here are payment to the provider for covered services rendered and do not represent funds held in trust for another. As the Presiding Officer noted, model codes may establish specific frameworks to appropriately define qualifications to meet desired objectives of that particular profession and, thus, professional codes regarding the commingling of funds for lawyers and realtors are not relevant to the discussion here.

The State further represents that SPA 11-011 does not violate section 1902(a)(23), because it does not directly target choice. Instead, the State claims that the SPA 11-011 holds out a "choice–neutral participation standard" with the "incidental effect of reducing patient choice." The State argues that past CMS decisions on other State plans demonstrate that CMS has allowed the "incidental" restriction of individuals from receiving covered services from entities that are otherwise fit to provide the services for any number of reasons. The State refers to *Kelly Kare, Ltd v. O'Rourke,* 930 F. 2d 170, 178 (2d Cir. 1991), in which the court upheld the termination of a provider agreement, notwithstanding the "lost choice," as it was an "incidental" burden on the right to choose under section 1902(a)(23) of the Act. The State also refers to several approved State plan provisions, which it claims respectively show the same principle. This includes CMS allowing the State of Indiana not to add additional beds for Medicaid in otherwise qualified nursing facilities even when additional patients might have wanted to use them (State Exhibit 12); CMS allowing the State of Georgia to preclude patients from choosing providers who wish to maintain solo individual practices (State Exhibit 13); CMS allowing the State of Louisiana to prohibit Medicaid patients from choosing prosthetic and orthopedic service providers that do not adopt a mission statement or prohibit smoking in the facility (State Exhibit 14); and CMS disapproving the State of Maryland's proposed SPA based on section 1902(a)(23), allegedly, because the State failed to demonstrate a sufficient number of providers (Exhibits 16-18). The State claimed that the only way to distinguish these situations from that presented in SPA 11-011 is based on policy preference and not the law.

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attaining true cost and revenue separation under the accepted accounting principles available.") A similar argument, regarding billing qualifications, is raised as a basis to "exclude" a provider and similarly fails. *See, supra,* Findings and Conclusion regarding section 1902(p)(1). *See also* Transcript of Oral Hearing at pp. 98, 125 in which witness clarified that regarding a provider that performed such noncovered services, the financial statements did not indicate any material "generally accepted accounting principle" or "GAAP" related deficiencies.

The court decision in *Kelly Kare, Ltd v. O'Rourke, supra,* does not further the State's arguments on this issue. *Kelly Kare* involved a home health care provider whose patients alleged that they were deprived of due process when the State cancelled the provider's contract without providing a termination hearing. The court held that: "We read *O'Bannon* as holding that a Medicaid recipient's freedom of choice rights are necessarily dependent on a provider's ability to render services. No cognizable property interest can arise in the Medicaid recipient unless the provider is both qualified and participating in Medicaid." The court found that: "refusal by a social services district to enter a contract with a qualified provider in no way affected the status of the provider which remains free to seek a [Medicaid] contract with a different social services district." In contrast, even assuming, *arguendo* the constitutional holding was correct in *Kelly Kare*, the present review of SPA 11-011 is whether the SPA substantively meets the applicable Medicaid State plan statutory requirement and, unlike *Kelly Kare*, this review does not involve a procedural due process challenge. The SPA 11-011 impermissibly affects providers' "qualification" status and results in a Statewide, class-wide exclusion. In short, the facts and holding in the Court of Appeal for the Second Circuit in *Kelly Kare* does not resolve or determine the issue involved in this case.[72]

Moreover, the State's reference to other State plans also is not determinative here. The State of Indiana SPA 05-015 (Exhibit 12) allows the State to refuse to allow certified nursing facilities to add additional beds, under certain circumstances, when regional occupancy is less than 95 percent. Preventing nursing facility from having excessive beds when occupancy rates do not require it, is directly related to the States rate setting powers and, *inter alia*, need to assure that payments are consistent with efficiency, economy, and quality of care as excess beds would pass excess costs onto Medicaid.[73] In contrast, the SPA 11-:011 at issue in this case was not promulgated under the State's rate setting authority.[74]

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[72] Further, as noted by CMS, *Kelly Kare*, to the extent it has been cited by the Court of Appeals for the Seventh Circuit (in *Bruggemann v. Blagojevich*, 324 F. 3d 906 (7th Cir. 2003), it is for the "noncontroversial proposition that the aim of the 'freedom of choice' provision is 'to give the recipient a choice among the available facilities, not to require the creation or authorization of new facilities.' "

[73] *See also* CMS' detailed discussion of the special rules applicable to nursing home bed expansions, and the link to State Medicaid funding budgetary constraints, which represents an issue not present in this case. CMS Brief at 20. *See also* CMS Post-Hearing Brief at n.5, which explains that the "good cause" criteria referred to therein, is reference to regulations that apply specifically to skilled nursing and intermediate care facilities for the mentally retarded and is not applicable here.

[74] *See also* CMS Post-Hearing Brief at n.5, which explains that the "good cause" criteria referred to therein, is reference to regulations that apply specifically to skilled nursing and intermediate care facilities for the mentally retarded.

The State of Georgia's approved State plan (Exhibit 13) does not allow individual providers to enroll as a provider of community mental health rehabilitative services. The nature of the community mental health rehabilitative services requires a coordinated care plan based on a range of practitioners (including individual practitioners) either employed or contracted/affiliated with the agency. This plan provision is consistent with the statutory and regulatory requirements for provider qualifications based on the State's determination that certain services can only be supplied at high quality though an "agency model." Thus, the State plan was consistent, *inter alia*, with the State's authority to provide reasonable qualifications for providers.

The State of Louisiana's State plan (Exhibit 14) requires that prosthetics and orthopedic service providers to be accredited by either of two national organizations. The State claims that this allows the State to limit choice based on a provider's failure to have a mission statement or because it allows smoking in the facility. A State may adopt accreditation standards issued by a national standard setting body under section 1902(a)(22) of the Act. Generally, accreditation standards are primarily developed for, and thus reasonably related to, a provider's ability to perform and properly bill for services.[75] Accreditation is a recognized process in which certification of competency, authority, or credibility is presented. The State of Louisiana plan is consistent with the State's authority to provide reasonable standards of qualifications to ensure that providers are capable of providing services of acceptable quality and to assure fiscal responsibility.

The State also referenced State Exhibits 16, 17, and 18, which involved Maryland State plan amendment disapprovals. Contrary to the State's contentions, the SPAs were disapproved because they, *inter alia*, violated the free choice of provider provision at section 1902(a)(23) of the Act. The free choice of provider provision was a separate basis of the disapproval from the criteria of whether a SPA will provide assurances that there are sufficient providers in the State. Whether a SPA will provide assurances that it meets the requirement that there are sufficient providers in the State is distinct and separate from the free choice of provider

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[75] The purpose of the American Board for Certification in Orthotics, Prosthetics and Pedorthics, Inc. (ABC) explains that: "The mission of the American Board for Certification in Orthotics, Prosthetics and Pedorthics, Inc. (ABC) is to establish and promote the highest standards of organizational and clinical performance in the delivery of orthotic, prosthetic and pedorthic services. The ABC fulfills this mission by: Measuring patient care provider's knowledge and skills through rigorous credentialing programs; Establishing standards of organizational performance through facility accreditation; Mandating Professional Continuing Education to maintain competency; Administering a Professional Discipline program; Communicating the value and importance of ABC credentials. http://www.abcop.org/about/Pages/Mission.aspx

requirement. Furthermore, a SPA can be disapproved, under section 1902(a)(23), even where the SPA does not directly eliminate a recipient's *existing* choice of providers, such in the subject SPAs, where a State was adding a new package of services. Therefore, the State's proposition, that SPA 11-011 will not cause a significant reduction of providers is not determinative of whether the SPA 11-011 violates the free choice of provider requirement.

The SPA does not address, nor does the State allege as rationale for the SPA, any rate setting or reasonable standards for provider qualification for performance of the services as those terms are commonly used and defined and authorized under the Medicaid program. Further, describing the exclusion of this class of provider as an "incidental" effect of reducing patient choice is not an accurate characterization of SPA 11-011's function. The SPA 11-011 does not remove providers from the Medicaid program, because they are in any sense unqualified "to perform the service or service required," which would be permissible under section 1902(a)(23). Rather, SPA 11-011 prevents Medicaid recipients who currently receive covered services from affected providers from being able to continue to receive covered services from the provider of their choice, simply because the State does not approve of the scope of the providers' non-Medicaid covered scope of practice. Eliminating Medicaid recipients' ability to choose to receive services from qualified providers is not an "incidental," "collateral," or somehow an accidental effect of SPA 11-011, but rather it is the explicit purpose of the SPA 11-011.

The SPA 11-011 has no relation to a provider's fitness to perform the service or services required, but instead, SPA 11-011 removes qualified providers from the Medicaid program based solely on the scope of their non-Medicaid covered scope of practice. However, section 1902(a)(23) does not only prohibit States from limiting all choice of providers, but guarantees to every Medicaid individual the right to choose any qualified provider that undertakes to provide the services to them.

<u>Section 1902(p)(1) of the Act</u>

Notwithstanding the unambiguous language of section 1902(a)(23) of the Act, the State also argues that section 1902(p)(1) of the Act and the legislative history of section 1902(p)(1) confers on States the authority to enact provider "qualifications" such as those set forth in SPA 11-011.[76] The State argues that the plain text, "[i]n addition to any other authority, a State may exclude any individual or entity ... for any reason for which the Secretary could exclude the individual or entity from participation in [Medicare]" gives States plenary

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[76] *See, e.g.,* State's Pre-Hearing Memorandum at 17-22. Indiana cites the following sentence from the Senate Finance Committee Report that accompanied the section 1902(p)(1) enactment. "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." *See also* Senate Report 100-109 at 14 (July 14, 1987).

(though not "unfettered," or arbitrary and capricious) power to set qualification standards.[77] The State also claimed that: "Indiana does not presume that States always had plenary authority over Medicaid qualifications, but instead treats [section 1902(p)(1)] as a grant of additional authority. It is CMS, not Indiana that contends that [section 1902(p)(1)] added nothing new, but merely clarified the rules concerning qualification that already existed."[78]

However, under section 1902(p)(1), the cross-referenced sections of the Social Security Act (sections 1128, 1128A or 1866(b)(2) of the Act) refer to mandatory or permissive exclusions of providers for various forms of malfeasance such as fraud, drug crimes, and failure to disclose necessary information to regulators, etc. The phrase "[i]n addition to any other authority" indicates that the cross-reference provisions are a non-exclusive list of specific grounds upon which States may bar providers from participating in Medicaid and does not support a proposition that States have an unlimited additional authority to exclude providers for any reason. The phrase merely confirms that the 1987 amendments were not intended to restrict States' existing exclusion authority, that were coextensive with the Secretary's exclusion authority under the named sections.[79] The phrase at issue in section 1902(p)(1), "in addition to any other authority", did not grant new "additional" authority to the States, but clarified existing authorities in *current Medicaid law*.[80] If the introductory clause in section 1902(p)(1) of the Act were a grant of new plenary exclusion authority to the States, that which follows would also be impermissibly redundant and unnecessary. That is, the specific grant of authority to States to exclude providers for the reasons specified in sections 1128, 1128A and 1866(b)(2) of the Act would be unnecessary if the clause at issue were a grant of "plenary" power.

The State also argues that the broad language of section 1902(p)(1) of the Act, enacted in 1987, after the establishment of the free choice of provider amendment, implicitly swept away the language at section 1923(a)(23) of the Act that grants States the authority to not pay for services furnished by a "provider ...convicted of a felony offense that the State

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[77] *Id.*

[78] State Pre-Hearing Reply Brief at 18.

[79] Regarding the States' coextensive authorities, States have historically had certain authorities with respect to Medicaid-related "fraud" and "abuse", as defined by the Medicaid program and responsibilities under the State plan for the exclusion of providers from the Medicaid program. *See e.g.* former 42 CFR Part 455, *See also* foregoing historical review of fraud and abuse provisions at 20-31.

[80] As noted by the Senate Committee on Finance Report: "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 of the reasons that constitute a basis for an exclusion from Medicare under sections 1128, 1128A, or 1866(b)(2) of the Social Security Act." S. Rep. No. 100–109, at 20 (1987) (emphasis added), *reprinted in* 1987 U.S.C.C.A.N. 682, 700.

determines is inconsistent with the *best interest of beneficiaries under the State plan*."[81] (Emphasis added.) Therefore, this language in section 1902(a)(23) of the Act was not redundant, under the State's interpretation, as it was just rendered obsolete. However, this proposition discounts the basic rule of statutory construction that all words in a statute are to be read to give effect. More importantly perhaps, section 4724(d)(2) of the Balanced Budget Act of 1997,[82] effective August 5, 1997 (and after the establishment of section 1902(p)(1) of the Act), amended paragraph section 1902(a)(23) by inserting the allegedly "swept away" restrictive language concerning felony convictions.[83] Significantly, Congress apparently determined such language in section 1902(a)(23) of the Act, which allows a State to not pay for medical assistance services provided by "persons or entity convicted of a felony under federal or State law for an offenses which the state agency determines is inconsistent with the best interests of beneficiaries under the State plan" was required even after the enactment of section 1902(p)(1) of the Act. No doubt this is because section 1902(p)(1) of the Act only *clarified* existing Medicaid law, which had already authorized States to act, but only based on Medicaid-related and defined "fraud" and "abuse" issues. In contrast, the amendment to section 1902(a)(23) expanded very narrowly the States' authority to allow action on persons and entities "convicted of a felony" under Federal or state law "which the state agency deems is inconsistent with *the best interest of the beneficiaries under the state plan*." (Emphasis added.) This very narrowly expanded authority gives no support to the basis for the SPA in this case.

The plain language of section 1902(p)(1) of the Act also addresses a State's authority to "exclude" providers, not to set provider "qualifications." The State is attempting to use the "exclusion" provision at section 1902(p)(1), as interchangeable with the "qualification" provision at section 1902(a)(23) of the Act. However, the statutory use of the term "qualified" is distinct from the use of the term "exclude." To "exclude" a provider means to refuse to enter into or terminate a participation agreement and exclusion means the service or items will not be reimbursed by Medicaid.[84] In order to exclude a provider, a State is required to grant the provider notice of the intent to "exclude" and an opportunity to appeal the exclusion.[85] Therefore, a State's authority to "exclude" a provider is not the same as the State's power to set reasonable and relevant Medicaid standards for provider "qualifications." If Congress had intended section 1902(p) to establish a State's authority to set "qualifications," it certainly could have used that term instead in that provision, but it did not choose to do so. Therefore even assuming, *arguendo*, the State had been granted

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[81] State's Prehearing Reply Brief at 20.

[82] Pub. Law 105-33.

[83] *See also* n. 24 for text of section 1902(a)(23) prior to the MMPPPA of 1987 and for relevant history. Congress in fact revisited section 1902(a)(23) of the Act, when section 1902(p)(1) was added in 1987. S*ee Id.*

[84] *See e.*g. Section 1902(p)(1) of the Act.

[85] 42 CFR 1002.212; 42 CFR 1002.213.

expansive powers under section 1902(p)(1) to "exclude" a provider for any reason established by State law whether it was related to program integrity or standards of care, that power to "exclude" would not mean it could "disqualify" (i.e., find not meeting "qualifications") an entire class of providers based on services they offer outside of the Medicaid program.

The State counters that the State law embodied in the HEA 1210 provides for due process and that the focus is "singular" and "provider-focused." Generally, the exclusion authority found in section 1902(p)(1) of the Act also does not contemplate the wholesale expulsion of entire classes of providers that have not demonstrated a lack of fitness to participate in the Medicaid program and have not been afforded any due process. The Medicaid statute and regulations, as well as State law, contemplates that providers are to be excluded on an individual basis, after being afforded due process, and only for reasons consistent with the fraud and abuse basis set forth in sections 1128, 1128A and 1866(b)(2). Appropriately, for example, 405 Ind. Admin. Code §1-1-6 sets forth the sanctions and the basis for the State's bases for exclusion which are limited to 11 grounds after investigation by the office, the office's designee, the Indiana Medicaid Fraud Control Unit (authorized under section 1903(q)) or other governmental authority. These grounds include such offenses as the submission of undocumented, false, fraudulent, or overstated claims; conduct abusive of the Medicaid program; breach of a Medicaid provider agreement; and failure to correct deficiencies or repay an over payment.

The foregoing due process provision, which the State contends is in place under HEA 1210 when a participation agreement is terminated or not renewed for the scope of a providers non-covered practice, is not explicitly set forth in the HEA or the applicable process provisions.[86] In addition, any alleged HEA 1210 exclusionary appeal process, at most, would

[86] *See* 405 Ind. Admin. Code 1-1-6 Sanctions against providers; determination after investigation. ("Sec. 6. (a) If, after investigation by the office of Medicaid policy and planning (office), the office's designee, the Indiana Medicaid fraud control unit (IMFCU), or other governmental authority, the office determines that a provider has violated any provision of IC 12-15, or has violated any rule established under one (1) of those sections, the office may impose one (1) or more of the following sanctions: **** (2) Reject a prospective provider's application for participation in the medical assistance program. (3) Remove a provider's certification for participation in the medical assistance program (decertify the provider). **** (b) Specifically, the office may impose the sanctions in subsection (a) if, after investigation by the office, the office's designee, the IMFCU, or other governmental authority, the office determines that the provider: (1) submitted, or caused to be submitted: (A) claims for medical assistance services: (i) that cannot be documented by the provider; or (ii) provided to a person other than a person in whose name the claim is made; (B) any false or fraudulent claims for medical assistance services or merchandise; (C) information with the intent of obtaining greater compensation than that which the provider is

be to determine whether the singular provider was properly found to be a member of a "class" of providers identified only by the specified scope of their non-covered practice, and not by any provider specific Medicaid fraud or abuse activities. The State has set forth SPA 11-011 as a prophylactic rule, excluding an entire class of providers based on the scope of their noncovered practice and not on any provider-specific-findings of Medicaid-related "fraud" and "abuse" as those terms are reasonably understood and defined under the Medicaid program.[87]

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legally entitled, including charges in excess of the: (i) fee schedule; or (ii) usual and customary charges; or (D) false information for the purpose of meeting prior authorization requirements; (2) engaged in a course of conduct or performed an act deemed by the office to be abusive of the Medicaid program or continuing the conduct following notification that the conduct should cease; (3) breached, or caused to be breached, the terms of the Medicaid provider certification agreement; (4) failed to comply with the terms of the provider certification on the Medicaid claim form; (5) overutilized, or caused to be overutilized, the Medicaid program; (6) submitted, or caused to be submitted: (A) a false or fraudulent provider certification agreement; (B) claims for medical assistance services for which federal financial participation is not available; or (C) any claims for medical assistance services or merchandise arising out of any act or practice prohibited by the: (i) criminal provisions of the Indiana Code; or (ii) rules of the office; (7) failed to: (A) disclose or make available to the office, the office's designee, the IMFCU, or other governmental authority, after reasonable request and notice to do so, documentation of services provided to Medicaid recipients and Medicaid records of payments made therefor; (B) comply with the requirements of 1902(a)(68) of the Social Security Act, except that such failure shall first be sanctioned with a corrective action plan before any other sanction in subsection (a) shall be applied; or (C) meet standards required by the state of Indiana or federal law for participation; (8) charged a Medicaid recipient for covered services over and above that paid for by the office; (9) refused to execute a new provider certification agreement when requested to do so; (10) failed to: (A) correct deficiencies to provider operations after receiving written notice of these deficiencies from the office; or (B) repay or make arrangements for the repayment of identified overpayments or otherwise erroneous payments.... or (11) billed the Medicaid program more than the usual and customary charge to the provider's private pay customers.") In accordance with the Federal Medicaid regulations, the Indiana exclusion statute also provides for notice, and appeal to an administrative law judge. *See, e.g.*, 405 Ind. Code §1-1-6(c); Id at § 1-1.5-2.

[87] The State also contends that the SPA and HEA 1210 were established to prevent "abuse" of Medicaid through the indirect subsidizing of noncovered services through the payment of properly billed and covered family planning services. The use of the term "abuse", in such a context, is not consistent with its definition under the Medicaid program or as generally used in the healthcare context. Medicaid "abuse" is defined as meaning "provider practices that are inconsistent with sound fiscal, business, or medical practices, and result in an unnecessary cost to the Medicaid program, or in reimbursement for services that are not

Further, the broad authorities that the State claims adheres to States under section 1902(p)(1) to exclude a provider for any reason allowed under State law, would further nullify the specific and carefully circumscribed exceptions allowed under the waiver provisions of section 1915 and referenced in section 1902(a)(23) of the Act (as applied to non-family planning services only). The waiver provisions at section 1915, *et seq*., are more limiting and restrictive on States than those proposed by the State here and would become impermissibly void under such an expansive interpretation of State power.

The State also relies on a Senate Report explaining that section 1902(p)(1) of the Act is "not intended to preclude a State from establishing, under State law, any other bases for excluding individuals or entities from its Medicaid program."[88] However, the Senate Report only proposes that section 1902(p)(1) does not have preemptive effect. Further, the same Senate Report states that section 1902(p)(1) is intended to protect the Medicaid program "from fraud and abuse and to protect the beneficiaries of those programs from incompetent practitioners and from inappropriate or inadequate care."[89] As true for all legislative history, the Senate Report does not and cannot alter, or make more expansive, the plain meaning of the statutory language, including the conventional use of the term "qualified" as that term is used in section 1902(a)(23) of the Act, or, in contrast, the term "exclude" as used in section 1902(p)(1). The Senate Report in whole merely emphasizes that the overarching purpose of section 1915(p)(1) is to assure the State's current and existing authority to exclude a provider based on the provider's quality of services and fiscal integrity (e.g., matters that fall under the definition of fraud and abuse under the Medicaid program). The Senate Report does not support a reading that allows State exclusions under any State policy interest, including the scope of a provider's services outside of Medicaid.

The State also erroneously looks to section 1128(b)(14) of the Social Security Act, which allows States to exclude providers who are in default on their student-loan payments as analogous to the State's action in SPA 11-011. The State argues that the scope of the type of exclusion to be allowed is not necessarily related to patient care or the Medicaid program. The State proposed that if the States may refuse to subsidize student-loan delinquents with

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medically necessary or that fail to meet professionally recognized standards for health care...." *See, supra.*

[88] S. Rep. No. 100–109, at 20 (1987) (emphasis added), *reprinted in* 1987 U.S.C.C.A.N. 682, 700.

[89] *Id.* at 1-2, 682. *See also* CMS Presiding officers recommended decision at n. 66, discussing further legislative history that the bill authorized exclusions in a number of situations including conviction for other crimes relating to fraud, theft, controlled substance abuse, revocation, or suspension of license, submission of excess charges claims for unnecessary services or substandard care. House Report at 133 Cong. Rec. H6809-01; 1987 WL 943548 (July 30, 1987). *See also* CMS Hearing Brief at pp. 12-15, n. 9.

Medicaid dollars, then they must have the authority to "avoid indirect financing" of any "non-Medicaid" conduct. However, this statute merely stipulates a particular and specifically congressionally authorized ground for excluding a Medicaid provider and does not support the proposition that the States may thus establish *any* rule of "exclusion" and declare it a provider "qualification" for purposes of section 1902(a)(23) of the Act. Such a broad reading would make the free choice of provider requirement superfluous, ineffectual, and without any force of law.[90]

In addition to the statutory language at section 1902(p)(1) of the Act and its legislative history, the State also relied on the implementing regulatory language at 42 CFR 1002.2 which states that: "In addition to any other authority it may have, a State may exclude an individual or entity from participation in the Medicaid program for any reason for which the Secretary could exclude that individual or entity from participation in the Medicare, Medicaid and other Federal health care programs under sections 1128, 1128A or 1866(b)(2) of the Social Security Act" and that "Nothing contained in this part should be construed to limit a State's own authority to exclude an individual or entity from Medicaid for any reason or period authorized by State law." The State maintained that the Presiding Officer's reliance on the placement of this text in the OIG section, instead of the language of the text itself, is insufficient to neutralize section 42 CFR 1002.2(b) as this regulation specifically authorizes State agencies to exclude on their own initiative. The State claims that nothing in this language limits a State to exclusions based on fraud and abuse. However, this regulatory language parallels the language in the statute and can confer no more exclusionary authority to the State than contained therein. Moreover, the history of the regulations and their legislative sources make evident, as noted, that States have had certain dual coextensive powers as to prosecuting and investigating Medicaid-related fraud and abuse issues, but such powers, under the Medicaid statute, have never extended to any State policy interest. In addition to the problem encountered by the State using the terms "exclude" and "qualified" interchangeably, the regulatory language relied upon by the State does not empower the State to "exclude" a provider from Medicaid for a reason unrelated to those historically

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[90] In addition, pursuant to the notice and rulemaking process for the OIG regulations implementing this provision, a commenter claimed that "that there is little relationship between failure to pay one's scholarship obligations and the right to participate in Medicare" The OIG responded that: "A physician reaps financial benefits from participating in Medicare and Medicaid. There is plainly a connection between requiring a physician who is benefitting from government programs to meet his or her financial obligations to the government, by repayment of loans. These regulations are a proper interpretation of statutory authority (section 1128(b)(14) of the Act)." 57 Fed. Reg. 3298, 3312 (Jan. 29, 1992)("Office of Inspector General 42 CFR Parts 1001, 1002, 1003, 1004, 1005, 1006 and 1007 Health Care Programs: Fraud and Abuse; Amendments to OIG Exclusion and CMP Authorities Resulting From Public Law 100-93.")

Medicaid-related program integrity and competency matters that arise under the Medicaid fraud and abuse provisions.

The exclusion process considered under section 1902(p)(1) is wholly distinct from the SPA submission requirements and the free choice of provider provision set forth at section 1902(a)(23) of the Act. The statute provides that Medicaid beneficiaries "may obtain [medical] assistance from any institution, agency ... or person qualified to perform the services or service required." The SPA 11-011 does not seek to exclude providers within the meaning of the Medicaid program but rather seeks to impose an expansive "qualification" not related to standards of care, rate setting, fiscal integrity or recordkeeping issues. If States are free to set any qualifications, no matter how unrelated to a provider's fitness to treat Medicaid patients, than the free-choice-of-provider requirement would be easily undermined or eliminated by simply labeling any exclusionary rules as a "qualification."

State's Notice of Intent

Finally, the regulation at 42 CFR 430.88 contemplates the opportunity for the submission of additional evidence and argument and, thus, it was permissible for the State to submit the Notice. The Administrator finds that the State's "Notice of Intent" to provide an affiliate option is insufficient to bring SPA 11-011 into compliance with section 1902(a)(23) of the Act. The State contends that the Notice clarifies the SPA's use of the word "entity that performs abortions or maintains or operates where abortions are performed" as not including a "separate affiliate of such entity if the entity does not benefit, even indirectly, from government contracts or grants awarded to the separate affiliate." However, the "Notice of Intent" was issued after the submission of SPA 11-011 to CMS and the CMS' disapproval. The Notice of Intent is not binding on the State.[91] Because the Notice was issued after the submission and disapproval of the SPA its language is not incorporated as part of the submitted proposed SPA material to be incorporated as part of the State plan. The "Notice of Intent" likewise does not describe a potential final policy and the criteria which an affiliate could satisfy to meet this rule. The "Notice of Intent" does not explain, inter alia, the nature of hypothetical affiliate arrangement and what the State would regard as an "opportunity" to "subsidize" abortion. Thus, the "Notice of Intent" is not sufficient to bring

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[91] *See, e.g.,* Transcript of Oral Hearing at 160-161 (Q: Now that was issued after CMS's denial and it's also a proposed rule, so as far as today's proceeding, what legal, significance, if any does it [have]. A: Oh, none, because they have issued the notice of proposed rulemaking before the preliminary injunction. The preliminary injunction came down. There's no point in proceeding with the rulemaking for a statute we can't enforce is the thinking there so there is no legal binding significance. It's only a statement of here's what we would be doing if we had a law to enforce. And so we don't know what that rule would look like ....")

SPA No. 11-011 into compliance with the free choice of provider requirement at section 1902(a)(23) of the Act and the regulation at 42 CFR 431.51.

Summary

The Administrator's disapproval notice correctly found that section 1902(a)(23)(A) of the Social Security Act (Act) provides that beneficiaries may obtain covered services from any qualified provider that undertakes to provide such services. The SPA 11-011 would disqualify otherwise qualified providers from participation in the State's Medicaid program and thereby limit the choice of qualified providers for Medicaid beneficiaries as prohibited under section 1902(a)(23) of the Act for reasons not related to their qualifications to provide such services. A State's Medicaid programs may not exclude qualified health care providers from providing services that are funded under the program because of a provider's scope of practice. Such a restriction would have a particular effect on beneficiaries' abilities to access family planning providers, which are subject to additional protections under section 1902(a)(23)(B) of the Act. Therefore, the Administrator correctly concluded that he could not determine that the proposed amendment complied with section 1902(a)(23) of the Act and, therefore, correctly disapproved SPA 11-011.

Decision

The CMS Presiding Officer's recommended decision on reconsideration is adopted as modified in accordance with the foregoing opinion. The SPA 11-011 is disapproved.

THIS CONSTITUTES THE FINAL ADMINISTRATIVE DECISION OF THE SECRETARY OF HEALTH AND HUMAN SERVICES

Date: MAY 2 3 2013

Marilyn Tavenner
Administrator
Centers for Medicare & Medicaid Services