

# Key Changes and New Interpretations Involving the Phase III Regulations

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Highlights of Important Changes Involving Several Exceptions and the New “Stand in the Shoes” Doctrine

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This article discusses certain aspects of the final Phase III regulations promulgated by the Department of Health and Human Services (HHS) on September 5, 2007.<sup>1</sup> The Phase III regulations amended HHS’ prior promulgated regulations regarding the legislation commonly known as Stark II, the physician self-referral prohibition in Section 1877 of the Social Security Act.<sup>2</sup>

Although the Phase III regulations and preamble provided a multitude of changes to the rules attendant to Stark II and new interpretations of the Centers for Medicare & Medicaid Services (CMS) of such rules, this article focuses on the changes to, and CMS’ new interpretations of, the following: (i) the physician recruitment exception; (ii) the rental of office space exception; (iii) the rental of equipment exception; and (iv) the personal service arrangements exception. Additionally, this article discusses the new “stand in the shoes” doctrine promulgated in the Phase III regulations.

By way of background, the legislation commonly known as Stark I was initially enacted in 1989 to prohibit referrals of Medicare patients for clinical laboratory services by physicians with financial relationships to such laboratories. In 1995, the scope of Stark II<sup>3</sup> was expanded to include additional types of services and, indirectly, Medicaid referrals.

Stark II defines these “designated health services” as<sup>4</sup>: (i) clinical laboratory services; (ii) physical therapy services; (iii) occupational therapy services; (iv) radiology services, including magnetic resonance imaging, computerized axial tomography scans, and ultrasound services;

(v) radiation therapy services and supplies; (vi) durable medical equipment and supplies; (vii) parenteral and enteral nutrients, equipment, and supplies; (viii) prosthetics, orthotics, and prosthetic devices and supplies; (ix) home health services; (x) outpatient prescription drugs; and (xi) inpatient and outpatient hospital services (collectively, designated health services, or DHS).

If a physician or a member of the physician's immediate family has a "financial relationship" (hereinafter defined) with a health care entity, then the physician may not make a referral to that entity for the furnishing of DHS under the Medicare and Medicaid programs, unless an exception applies.<sup>5</sup> An entity that renders any DHS based upon a referral from a physician with a "financial relationship" with the entity may not bill for the service under Medicare and Medicaid, unless an exception applies.<sup>6</sup>

There are two kinds of "financial relationships" under Stark II:<sup>7</sup> (i) ownership or investment interests; and (ii) compensation arrangements. Ownership and investment interests can be through debt, equity, or other means and can be indirect. Compensation arrangements can potentially include any remuneration to a physician. Accordingly, Stark II addresses very broad categories of activity.

Sanctions for violations of Stark II can include denial of payments, refund requirements, civil money penalties of up to \$15,000 for each service rendered, and exclusion from the Medicare and Medicaid programs.<sup>8</sup> Additional civil penalties may be triggered of up to \$100,000 by schemes designed to circumvent the statute<sup>9</sup> or of \$10,000 per day by failure to meet certain reporting requirements.<sup>10</sup>

On January 4, 2001, the Department of Health and Human Services promulgated Phase I regulations.<sup>11</sup> Most of the provisions of the Phase I regulations became effective on January 4, 2002, except for Section 424.22(d), which became effective April 6, 2001.<sup>12</sup> Thereafter, HHS promulgated the

Phase II regulations on March 26, 2004.<sup>13</sup> The Phase II regulations set forth the self-referral prohibition and applicable definitions, interpreted various exceptions of the self-referral prohibition set forth in the Stark II legislation, and created additional regulatory exceptions for arrangements that do not pose a risk of program or patient abuse.<sup>14</sup> The Phase II regulations became effective on July 26, 2004. The Phase III regulations, certain aspects of which are the focus of this article, were then promulgated by HHS on September 5, 2007.<sup>15</sup> Most of the provisions of the Phase III regulations become effective December 4, 2007.<sup>16</sup>

Stark II, as supplemented by the Phase I, Phase II, and Phase III regulations, contains numerous exceptions to Stark II's prohibitions, including but not limited to: (i) the physician recruitment exception; (ii) the rental of office space exception; (iii) the rental of equipment exception; and (iv) the personal service arrangements exception. Changes to such exceptions and CMS' interpretations thereto in the Phase III regulations' preamble are discussed below. Additionally, discussed below is the new "stand in the shoes" doctrine set forth in the Phase III regulations.

### **PHYSICIAN RECRUITMENT EXCEPTION<sup>17</sup>**

Section 1877(e)(5) of the Social Security Act<sup>18</sup> states that the physician recruitment exception applies "[i]n the case of remuneration which is provided by a hospital to a physician to induce the physician to relocate to the geographic area served by the hospital in order to be a member of the medical staff of the hospital if: (i) the physician is not required to refer patients to the hospital; (ii) the amount of the remuneration under the arrangement is not determined in a manner that takes into account (directly or indirectly) the volume or value of any referral by the referring physician; and (iii) the arrangement meets such other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse."

The Phase III regulations modified the Phase II regulations regarding the physician recruitment exception as follows:<sup>19</sup>

- (i) Allowing rural health clinics (in addition to hospitals and federally qualified health centers) to use this exception;
- (ii) Deeming the geographic area served by a hospital to be the area comprised of all of the contiguous zip codes from which the hospital's inpatients are drawn if the hospital draws fewer than 75 percent of its inpatients from contiguous zip codes;
- (iii) Allowing an alternative test to determine the "geographic area served by the hospital" for a hospital located in a rural area (*i.e.*, use of the lowest number of contiguous, or in some cases, noncontiguous, zip codes from which a rural hospital draws at least 90 percent of its inpatients);
- (iv) Allowing a more generous income guarantee in certain circumstances for a physician that a physician practice located in a rural area or health professional shortage area (HPSA) recruits to replace a deceased, retiring, or relocating physician;
- (v) Allowing group practices to impose certain practice restrictions on a recruited physician;
- (vi) Allowing rural hospitals to recruit physicians into an area outside of the hospital's geographic area if the Secretary of HHS determines through an advisory opinion that the area has a demonstrated need for the recruited physician;
- (vii) Exempting from the relocation requirement a physician who, for the two years immediately prior to the recruitment arrangement, was employed on a full-time basis by a federal or state bureau of prisons (or similar entity operating correctional facilities), the Department of Defense or Department of Veterans Affairs, or facilities of the Indian Health Service, as long as the physician did not maintain a separate private practice in addition to such full-time employment;
- (viii) Exempting from the relocation requirement those physicians whom the Secretary of HHS has deemed in an advisory opinion not to have an established medical practice comprised of a significant number of patients of the recruiting hospital;
- (ix) Clarifying that a physician must relocate his or her practice from outside the geographic service area to a location inside the service area and either: (a) move his or her medical practice at least 25 miles; or (b) have a new medical practice that derives at least 75 percent of its revenues from professional services furnished to patients (including hospital inpatients) not seen or treated by the physician at his or her prior medical practice site, during the preceding three years, measured on an annual basis (fiscal or calendar year); and
- (x) Clarifying that an income guarantee made by a hospital to a recruited physician who joins a physician practice applies to any type of income guarantee.

### General Conditions

The Phase III regulations reflect that the physician recruitment exception applies to remuneration provided by a hospital to recruit a physician that is paid directly to the physician and is intended to induce the physician to "relocate his or her medical practice" (as hereinafter defined) to the "geographic area served by the hospital" (as hereinafter defined) in order to become a member of the hospital's medical staff if all of the following conditions are met:

- The arrangement is set out in writing and signed by both the hospital and physician.
- The arrangement is not conditioned on the physician's referral of patients to the hospital.
- The hospital does not determine (directly or indirectly) the amount of the remuneration to the physician based on the volume or value of any actual or anticipated referrals by the physician or other business generated by the parties. (For

example, the unconditional payment of actual moving expenses of the recruited physician would not take into account the volume or value of referrals.<sup>20)</sup>

- The physician is allowed to establish staff privileges at any other hospital(s) and to refer business to any other entities.<sup>21)</sup>

CMS clarifies in the preamble to the Phase III regulations that the physician recruitment exception cannot be utilized if the physician is already a member of the hospital's medical staff<sup>22)</sup> and that such is the case even if the physician held courtesy privileges versus active privileges.<sup>23)</sup>

### **Definition of Geographic Area Served by the Hospital**

Regarding the physician recruitment exception, the Phase III regulations define "geographic area served by the hospital" to mean:

- The area composed of the lowest number of contiguous zip codes from which the hospital draws 75 percent of its inpatients.<sup>24)</sup>
- If a hospital draws fewer than 75 percent of its inpatients from all of the contiguous zip codes from which it draws its inpatients, then the "geographic area served by hospital" will be deemed to be the area composed of all of the contiguous zip codes from which the hospital draws its inpatients. (For example, if the zip codes contiguous to the hospital account for only 69 percent of the hospital's inpatients, then the hospital would be permitted to recruit into the zip codes from which it draws 69 percent of its inpatients.<sup>25)</sup>
- A special rule regarding the definition of "geographic area served by the hospital" applies if the hospital is located in a rural area<sup>26)</sup> (as hereinafter defined). If the hospital is located in a rural area, then the "geographic area served by the hospital" may also be the area composed of the lowest number of contiguous zip codes from which the hospital draws at least 90 percent of its inpatients. If the hospital draws fewer than 90 percent of

its inpatients from all of the contiguous zip codes from which it draws inpatients, the "geographic area served by the hospital" may include noncontiguous zip codes, beginning with the noncontiguous zip codes in which the highest percentage of the hospital's inpatients reside and continuing to add noncontiguous zip codes in decreasing order of percentage inpatients.

- "Rural area"<sup>27)</sup> means an area that is not an "urban area" (as hereinafter defined). "Urban area"<sup>28)</sup> means (i) a metropolitan statistical area (MSA) or New England County Metropolitan Area (NECMA), as defined by the Executive Office of Management and Budget; or (ii) the following New England Counties: Litchfield County, Connecticut; York County, Maine; Sagadahoc County, Maine; Merrimack County, New Hampshire; and Newport County, Rhode Island.

CMS also provides clarifications regarding the meaning of the "geographic area served by the hospital" including:<sup>29)</sup> (i) if multiple configurations containing the same number of zip codes permit the hospital to meet the applicable percent of inpatient threshold, the hospital may use any of the configurations; (ii) a hospital may use any configuration that satisfies the lowest number of zip codes/applicable percent of inpatients test on the date all parties have signed the written recruitment agreement (which may result in the use of different geographic service areas for different recruitment arrangements); and (iii) the determination of the geographic service area of the hospital is a hospital-specific determination, even if the hospital is part of a hospital system (meaning that the geographic area served by the hospital is determined at the hospital level, not the hospital system level).

### **Definition of Physician Relocates His or Her Medical Practice**

Regarding the physician recruitment exception, the Phase III regulations state

that a physician “relocates his or her medical practice” if the practice was located outside the geographic area served by the hospital *and*:

- The physician moves his or her medical practice at least 25 miles and into the geographic area served by the hospital; *or*
- The physician moves his medical practice into the geographic area served by the hospital, and the physician's new medical practice derives at least 75 percent of its revenues from professional services furnished to patients (including hospital inpatients) not seen or treated by the physician at his or her prior medical practice site during the preceding three years, measured on an annual basis (fiscal or calendar year).<sup>30</sup>

The physician will not be subject to the relocation requirement if (i) the physician is a resident or has been in practice one year or less; (ii) the physician was employed on a full-time basis for at least two years immediately prior to the recruitment arrangement by one of the following (and did not maintain a private practice in addition to such full-time employment): (A) a federal or state Bureau of Prisons to serve a prison population; (B) the Department of Defense or Department of Veterans Affairs to serve active or veteran military personnel and their families; or (C) a facility of the Indian Health Service to serve patients who receive medical care exclusively through the Indian Health Service; or (iii) if the Secretary of HHS deems in an advisory opinion that the physician does not have an established medical practice that serves or could serve a significant number of patients who are or could become patients of the recruiting hospital.

### **Special Rule if Recruited Physician is Joining a Physician Practice**

Regarding the physician recruitment exception, in the case of remuneration provided by a hospital to a physician either indirectly through payments made to another phy-

sician practice or directly to a physician who joins a physician practice, the Phase III regulations state that the following additional conditions must be met:

- *Signature requirement*: The written agreement referenced in the “General Conditions” hereinabove also must be signed by the party to whom the payments are directly made.
- *Remuneration to Recruited Physician Requirement*: Except for actual costs incurred by the physician practice in recruiting the new physician, the remuneration is passed directly through to or remains with the recruited physician.
- *Characteristics of Permissible Income Guarantee*: In the case of an income guarantee of any type made by the hospital to a recruited physician who joins a physician practice, the costs allocated by the physician practice to the recruited physician do not exceed the actual incremental costs attributable to the recruited physician.
- *Special Rule if Recruited Physician Joins Practice Located in Rural Area or HPSA*: If the recruited physician joins a practice located in a rural area or health professional shortage area (HPSA) and is recruited to replace a physician who, within the previous 12-month period, retired, relocated outside of the geographic area served by the hospital, or died, the costs allocated to the physician do not exceed either: (i) the actual additional incremental costs attributable to the recruited physician; or (ii) the lower of a *per capita* allocation or 20 percent of the practice's aggregate costs.
- *Recordkeeping Requirement*: Records of the actual costs and the passed-through amounts are maintained for a period of at least five years and made available to the Secretary of HHS upon request.
- *No Consideration of Referrals Requirement*: The remuneration from the hospital under the arrangement is not determined in a manner that takes into account (directly or indirectly) the volume or value of any actual or anticipated referrals by

the recruited physician or the physician practice (or any physician affiliated with the physician practice) receiving the direct payments from the hospital.

- *No Unreasonable Non-Competition Restrictions on Recruited Physician:* The physician practice may not impose on the recruited physician practice restrictions that unreasonably restrict the recruited physician's ability to practice medicine in the geographic area served by the hospital.
- *No Anti-Kickback Violations Requirement:* The arrangement does not violate the anti-kickback statute or any federal or state law or regulation governing billing or claims submission.

### **RENTAL OF OFFICE SPACE AND RENTAL OF EQUIPMENT EXCEPTIONS**

The Phase III regulations did not change the office space rental exception<sup>31</sup> or the equipment rental exception,<sup>32</sup> however, CMS clarified these exceptions' applicability in certain respects in the preamble to the Phase III regulations promulgated in the *Federal Register*.<sup>33</sup>

To be exempted from the Stark II prohibition against compensation arrangements, payments for rental of office space or equipment must:<sup>34</sup> (i) be made by a lessee to a lessor pursuant to a written lease that is signed by the parties and specifies the premises or equipment covered by the lease; (ii) covers only space or equipment that is reasonable and necessary for legitimate purposes and, except for certain allowable payments for common office space, is used exclusively by the lessee; (iii) provides for a term of at least one year (and if the lease is terminated, the parties may not enter into a new lease during the first year of the original term of the lease); (iv) contains charges for the property that are (a) set forth in advance, (b) consistent with fair market value, and (c) set in a manner that does not take into account referrals or an amount of business between the parties; and (v) is commercially reasonable even if no referrals were made between the parties.

Additionally, each of the office space and equipment rental exceptions allow for a holdover month-to-month rental for up to six months immediately following the expiration of an agreement of at least one year that meets the other requirements set forth in such exceptions.<sup>35</sup>

CMS' clarifications in the preamble to the Phase III regulations regarding the rental of office space and equipment exceptions included the following:

- The lessor and lessee may not change the rental charges at any time during the term of the lease.<sup>36</sup> CMS' rationale for such a conclusion is that the Stark II legislation and the regulations provide that the rental charges, including the methodology to calculate the rental charges, must be "set in advance."<sup>37</sup>
- If lessor and lessee desire to change the rental charges, the lease must be terminated, and a new lease must be entered into reflecting the different rental charges and/or terms.<sup>38</sup> The new lease may be entered into only after the first year of the original lease term (regardless of the length of the original term). The new lease must have a term of at least one year and comply with the other requirements of the office space or equipment exceptions.<sup>39</sup>
- The lessor and lessee may amend a lease multiple times during or after the first year of its terms as long as the rental charges are not changed and all other requirements of the office space or equipment exceptions are met.<sup>40</sup> CMS cautions that amendments to terms that are material to the rental charges, for example the amount of space leased, may cause the rental charges to not comply with the fair market value and not take into account referrals or an amount of business between the parties' requirements.<sup>41</sup>
- An amended lease does not need to continue for an additional one year following the date of the amendment if the original termination date would occur

sooner (as long as the original term of the lease was for at least one year and the other requirements of the office space or equipment exceptions are met).<sup>42</sup>

- Regarding office-sharing arrangements in which several physicians and/or groups share facilities and some limited equipment without exclusivity, CMS stated that since the office space and equipment exceptions require that the lessee have exclusive use of the leased space (with an exception for common areas if the rent is appropriately pro rated) or equipment when the lessee uses the space or equipment, the exceptions require that the space and equipment leases be for established blocks of time.<sup>43</sup> Thus, CMS' commentary means that CMS may view multiple physicians and or groups that share facilities on a non-exclusive, first-come-first-serve, as needed, basis, as not meeting the requirements of the office space and equipment exceptions.
- Lessors may charge a holdover rental premium, as long as the amount of the premium was set in advance in the lease at the time of its execution and the rental rate, including the premium, is consistent with fair market value, and does not take into account the volume or value of referrals or other business generated between the lessor and lessee.<sup>44</sup>
- The holdover period will not be extended beyond six months in cases where the lessor is trying to evict a tenant.<sup>45</sup>

#### **PERSONAL SERVICE ARRANGEMENTS EXCEPTION**

The Phase III regulations made a minor modification to the "personal services arrangements" exception to include a holdover provision similar to the holdover provisions in the rental of office space or equipment exceptions.<sup>46</sup> CMS also clarified the applicability of the personal service arrangements exception in certain respects in the preamble to the Phase III regulations promulgated in the *Federal Register*.<sup>47</sup>

Remuneration for specific physicians' services can be excepted from Stark II's prohibition against compensation relationships if the arrangement:<sup>48</sup> (i) is in writing, signed by the parties, and specifies the services it covers; (ii) covers all services the physician (or an immediate family member of the physician) will provide to the entity; (iii) involves only services that are reasonable and necessary for legitimate business purposes; (iv) the term of the arrangement is for at least one year; (v) sets forth compensation that does not exceed fair market value and is not determined based on the volume or value of referrals of any referrals or other business generated between the parties; and (vi) does not involve the counseling or promotion of activities that violate state or federal law.

Additionally, the personal services exception allows for a holdover for up to six months immediately following the expiration of an agreement of at least one year that meets the other requirements set forth in the exception.

CMS clarified in the preamble to the Phase III regulations that a personal services contract may be amended in the same manner as an office space or equipment lease.<sup>49</sup> This means, for example by way of illustration and not an exhaustive itemization, the following: if the contracting parties in a personal services arrangement desire to change the compensation, the agreement must be terminated, and a new agreement reflecting the different compensation terms should be entered into; the new agreement may be entered into only after the first year of the original agreement's term (regardless of the length of the original term); and the new agreement must have a term of at least one year and comply with the other requirements of the personal services arrangement exceptions.

#### **NEW "STAND IN THE SHOES" DOCTRINE**

The Phase III regulations included new provisions in 42 C.F.R. Section 411.351 and 42 C.F.R. Section 411.354 under which

a referring physician will be treated as “standing in the shoes” of his or her physician organization for purposes of applying rules that describe direct and indirect compensation arrangements. These new provisions clarify that certain compensation arrangements between a group practice or other “physician organization” (hereinafter defined) and an entity that provides DHS should be analyzed under the various direct compensation arrangement exceptions and not under the indirect compensation arrangement’s definition or exception.

The Phase III regulations amended 42 C.F.R. Section 411.354(c) to add a new subsection which states:<sup>50</sup>

A physician is deemed to have a direct compensation arrangement with an entity furnishing DHS if the only intervening entity between the physician and the entity furnishing DHS is his or her physician organization. In such situations, for purposes of this section, the physician is deemed to stand in the shoes of the physician organization.

“Physician organization” is newly defined in 42 C.F.R. Section 411.351 to mean “a physician (including a professional corporation of which the physician is the sole owner), a physician practice, or a group practice that complies with the requirements of” 42 C.F.R. Section 411.352.

Interestingly, however, on November 9, 2007, CMS made a final rule available for public inspection that delays the effective date for one year (*i.e.*, until December 4, 2008) of the “stand in the shoes” provision set forth in the Phase III regulations for the following compensation arrangements only: (i) compensation arrangements between a faculty practice plan and another component of the same academic medical centers as described in 42 C.F.R. Section 411.355(e) (2); and (ii) compensation arrangements

between a DHS entity affiliated with an integrated section 501(c)(3) health care system and an affiliated physician practice in the same integrated section 501(c)(3) health care system.

## CONCLUSION

This article discusses the highlights of the changes or additions to, and CMS’ interpretations of, the physician recruitment exception, the rental of office space exception, the rental of equipment exception, the personal service arrangements exception, and the new “stand in the shoes” doctrine promulgated in the Phase III regulations. Physicians, industry stakeholders, attorneys, and other counselors should regularly review Stark II and the attendant regulations to ascertain whether any changes have occurred or any new administrative or judicial interpretations have been promulgated thereto.

## Endnotes:

1. *Final rule*, 72 FR 51012, Sept. 5, 2007.
2. Stark II is set forth in Section 1877 of the Social Security Act (and is codified at 42 U.S.C. Section 1395nn). Stark II became effective January 1, 1995.
3. *Id.*
4. 42 U.S.C. § 1395nn(h)(6).
5. 42 U.S.C. 1395nn(a)(1)(A).
6. 42 U.S.C. 1395nn(a)(1)(B).
7. 42 U.S.C. 1395nn(a)(2).
8. 42 U.S.C. Section 1395nn(g)(1)(2) and (3).
9. 42 U.S.C. Section 1395nn(g)(4).
10. 42 U.S.C. Section 1395nn(g)(5).
11. *Final rule*, 66 FR 856, Jan. 4, 2001.
12. *Final rule*, 72 FR 51012, Jan. 5, 2007.
13. *Final rule*, 69 FR 16054, March 26, 2004.
14. *Id.*
15. *Final rule*, 72 FR 51012, Sept. 5, 2007.
16. *Id.*
17. The “physician recruitment” exception as discussed in this article will be effective December 4, 2007, and was published in 72 FR 51012-51099 (2007) as part of the new final rule, referred to as “Phase III”.
18. Codified at 42 U.S.C.A. Section 1395nn(e)(5).
19. *Final rule*, 72 FR 51012 at 51048, Sept. 5, 2007.
20. *Id.*
21. Except referrals may be restricted under an employment or services contract that complies with 42 C.F.R. Section 411.354(d)(4). A physician’s compensation from a *bona fide* employer or under managed care contract or other contract for personal services may be conditioned on

- the physician's referrals to a particular provider, practitioner, or supplier, provided that the compensation arrangement meets all of the conditions of 42 C.F.R. Section 411.354(d)(4).
22. *Final rule*, 72 FR 51012 at 51048, Sept. 5, 2007.
  23. *Id.* CMS states, "We are not persuaded that permitting recruitment of physicians who are not on a hospital's "active" medical staff, but who hold some type of medical staff privileges, poses no risk of program or patient abuse."
  24. The geographic area served by the hospital may include one or more zip codes from which the hospital draws no inpatients, provided that such zip codes are entirely surrounded by zip codes in the geographic area composed of the lowest number of contiguous zip codes from which the hospital draws 75 percent of its inpatients. (Note that the hospital may recruit a physician to establish a practice into the "hole" zip code. 72 Federal Register 51012 at 51050.).
  25. *Final rule*, 72 Federal Register 51012 at 51050, Sept. 5, 2007.
  26. Rural area is defined at 42 C.F.R. Section 411.351.
  27. *Id.*
  28. Urban area is defined at 42 C.F.R. Section 412.62(f)(1)(ii).
  29. *Final rule*, 72 FR 51012 at 51050-51051, Sept. 5, 2007.
  30. For the initial "start up" year of the recruited physician's practice the 75 percent test will be satisfied if there is a reasonable expectation that the recruited physician's medical practice for the year will derive at least 75 percent of its revenues from professional services furnished to patients not seen or treated by the physician at his or her medical practice site during the preceding three years.
  31. *Final rule*, 72 FR 51012 at 51091, Sept. 5, 2007.
  32. *Id.* at 51092.
  33. *Id.* at 51043- 51045.
  34. 42 C.F.R. Section 411.357(a) and 42 C.F.R. Section 411.357(b).
  35. 42 C.F.R. Section 411.357(a)(7) and 42 C.F.R. Section 411.357(b)(7).
  36. *Final rule*, 72 FR 51012 at 51044, Sept. 5, 2007.
  37. *See* 42 U.S.C. Section 1395nn(e)(1)(A)(iv); 42 U.S.C. Section 1395nn(e)(1)(B)(iv); 42 C.F.R. Section 411.357(a)(4); and 42 C.F.R. Section 411.357(b)(4).
  38. *Final rule*, 72 FR 51012 at 51044, Sept. 5, 2007.
  39. *Id.*
  40. *Id.*
  41. *Id.*
  42. *Id.*
  43. *Id.* at 51045.
  44. *Id.*
  45. *Id.*
  46. *Id.* at 51092.
  47. *Id.* at 51045-51047.
  48. *Id.* at 51092.
  49. *Id.*
  50. 42 C.F.R. Section 411.354(c)(ii).

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