

■ E. In paragraphs (b)(1), (b)(2), (c)(1), (c)(2) introductory text, (c)(3), (c)(4), (c)(5), and (c)(6) by removing the term “clinic” each time it appears and by adding in its place the term “RHC”.

■ F. In paragraphs (b)(1), (b)(2), (c)(1), (c)(2) introductory text, (c)(3), (c)(4), (c)(5) and (c)(6) by removing the term “center” each time it appears and by the term “FQHC”.

■ 35. Section 405.2472 is amended by revising paragraph (a) to read as follows:

§ 405.2472 Beneficiary appeals.

(a) The beneficiary is dissatisfied with a MAC’s determination denying a request for payment made on his or her behalf by a RHC or FQHC;

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

■ 36. The authority citation for part 410 continues to read as follows:

Authority: Sec. 1102, 1834, 1871, 1881, and 1893 of the Social Security Act (42 U.S.C. 1302, 1395m, 1395hh, and 1395ddd).

■ 37. Section 410.152 is amended by revising paragraph (f) to read as follows:

§ 410.152 Amounts of payment.

(f) *Amount of payment: Rural health clinic (RHC) and Federally qualified health center (FQHC) services.* Medicare Part B pays, for services by a participating RHC or FQHC that is authorized to bill under the reasonable cost system, 80 percent of the costs determined under subpart X of part 405 of this chapter, to the extent those costs are reasonable and related to the cost of furnishing RHC or FQHC services or reasonable on the basis of other tests specified by CMS.

PART 491—CERTIFICATION OF CERTAIN HEALTH FACILITIES

■ 38. The authority citation for part 491 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302); and sec. 353 of the Public Health Service Act (42 U.S.C. 263a).

■ 39. Section 491.8 is amended by revising paragraph (a)(3) to read as follows:

§ 491.8 Staffing and staff responsibilities.

(a) * * *

(3) The physician assistant, nurse practitioner, nurse-midwife, clinical social worker or clinical psychologist member of the staff may be the owner or an employee of the clinic or center,

or may furnish services under contract to the clinic or center. In the case of a clinic, at least one physician assistant or nurse practitioner must be an employee of the clinic.

PART 493—LABORATORY REQUIREMENTS

■ 40. The authority citation for part 493 is revised to read as follows:

Authority: Sec. 353 of the Public Health Service Act, secs. 1102, 1861(e), the sentence following sections 1861(s)(11) through 1861(s)(16) of the Social Security Act (42 U.S.C. 263a, 1302, 1395x(e), the sentence following 1395x(s)(11) through 1395x(s)(16)), and the Pub. L. 112–202 amendments to 42 U.S.C. 263a.

■ 41. Section 493.1 is amended by revising the second sentence to read as follows:

§ 493.1 Basis and scope.

* * * It implements sections 1861(e) and (j), the sentence following section 1861(s)(13), and 1902(a)(9) of the Social Security Act, and section 353 of the Public Health Service Act, as amended by section 2 of the Taking Essential Steps for Testing Act of 2012. * * *

■ 42. Section 493.2 is amended by adding the definition of “Repeat proficiency testing referral” in alphabetical order, to read as follows:

§ 493.2 Definitions.

Repeat proficiency testing referral means a second instance in which a proficiency testing sample, or a portion of a sample, is referred, for any reason, to another laboratory for analysis prior to the laboratory’s proficiency testing program event cut-off date within the period of time encompassing the two prior survey cycles (including initial certification, recertification, or the equivalent for laboratories surveyed by an approved accreditation organization).

■ 43. Section 493.1800 is amended by revising paragraph (a)(2) introductory text to read as follows:

§ 493.1800 Basis and scope.

(a) * * *

(2) The Clinical Laboratory Improvement Act of 1967 (section 353 of the Public Health Service Act) as amended by CLIA 1988, as amended by section 2 of the Taking Essential Steps for Testing Act of 2012—

■ 44. Section 493.1840 is amended by revising paragraph (b) to read as follows:

§ 493.1840 Suspension, limitation, or revocation of any type of CLIA certificate.

(b) *Adverse action based on improper referrals in proficiency testing.* If CMS determines that a laboratory has intentionally referred its proficiency testing samples to another laboratory for analysis, CMS does one of the following:

(1)(i) Revokes the laboratory’s CLIA certificate for at least 1 year, prohibits the owner and operator from owning or operating a CLIA-certified laboratory for at least 1 year, and may impose a civil money penalty in accordance with § 493.1834(d), if CMS determines that—

(A) A proficiency testing referral is a repeat proficiency testing referral as defined at § 493.2; or

(B) On or before the proficiency testing event close date, a laboratory reported proficiency testing results obtained from another laboratory to the proficiency testing program.

(ii) Following the revocation of a CLIA certificate in accordance with paragraph (b)(1)(i) of this section, CMS may exempt a laboratory owner from the generally applicable prohibition on owning or operating a CLIA-certified laboratory under paragraph (a)(8) of this section on a laboratory-by-laboratory basis if CMS finds, after review of the relevant facts and circumstances, that there is no evidence that—

(A) Patients would be put at risk as a result of the owner being exempted from the ban on a laboratory-by-laboratory basis;

(B) The laboratory for which the owner is to be exempted from the general ownership ban participated in or was otherwise complicit in the PT referral of the laboratory that resulted in the revocation; and

(C) The laboratory for which the owner is to be exempted from the general ownership ban received a PT sample from another laboratory in the prior two survey cycles, and failed to immediately report such receipt to CMS or to the appropriate CMS-approved accrediting organization.

(2) Suspends or limits the CLIA certificate for less than 1 year based on the criteria in § 493.1804(d) and imposes alternative sanctions as appropriate, in accordance with § 493.1804(c) and (d), § 493.1806(c), § 493.1807(b), § 493.1809 and, in the case of civil money penalties, § 493.1834(d), when CMS determines that paragraph (b)(1)(i)(A) or (B) of this section does not apply but that the laboratory obtained test results for the proficiency testing samples from another laboratory on or before the proficiency testing event close date. Among other possibilities, alternative

sanctions will always include a civil money penalty and a directed plan of correction that includes required training of staff.

(3) Imposes alternative sanctions in accordance with § 493.1804(c) and (d), § 493.1806(c), § 493.1807(b), § 493.1809 and, in the case of civil money penalties, § 493.1834(d), when CMS determines that paragraph (b)(1)(i) or (2) of this section do not apply, and a PT referral has occurred, but no test results are received prior to the event close date by the referring laboratory from the laboratory that received the referral. Among other possibilities, alternative sanctions will always include a civil money penalty and a directed plan of correction that includes required training of staff.

* * * * *

Dated: April 3, 2014.

Marilyn Tavenner,

Administrator, Centers for Medicare & Medicaid Services.

Approved: April 9, 2014.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

Note: The following Addendum will not appear in the Code of Federal Regulations.

Addendum: FQHC Geographic Adjustment Factors (FQHC GAFs)

As described in section II.C.2. of this final rule with comment period, we used the CY 2015 GPCI values and cost share weights, as published in the CY 2014 PFS final rule with comment period, to model the geographic adjustments for the FQHC PPS rates. The FQHC GAFs that will be used for payment under the FQHC PPS will be adapted from the GPCIs used to adjust payment under the PFS for that same period.

The 2014 FQHC GAFs in the following table are adapted from the CY 2014 PFS GPCIs, as finalized in the CY 2014 PFS final rule with comment period. The 2014 FQHC GAFs are the

values that will be used to adjust payment under the FQHC PPS for the period of October 1 through December 31, 2014. The 2014 FQHC GAFs in the following table do not reflect the 1.0 floor on the PFS work GPCI that is effective from January 1, 2014, through March 31, 2014, which was authorized by the Pathway for SGR Reform Act of 2013.

The 2015 FQHC GAFs in the following table are adapted from the CY 2015 PFS GPCIs, as finalized in the CY 2014 PFS final rule with comment period. The 2015 FQHC GAFs listed were used to model the geographic adjustments for the FQHC PPS rates. Under current law and regulation, these same values would be used to adjust payments under the FQHC PPS during CY 2015.

We note that updates to the PFS GPCIs due to changes in law or implemented through regulation would also apply to the FQHC GAFs, such as changes to the CY 2015 PFS GPCIs that may be included in the final CY 2015 PFS rule. The FQHC GAFs would be recalculated and updated through program instruction so that they remain consistent with the PFS GPCIs.

Locality name		2014 FQHC GAF	2015 FQHC GAF
1 Alabama		0.933	0.936
2 Alaska		1.307	1.316
3 Arizona		0.985	0.993
4 Arkansas		0.920	0.920
5 Anaheim/Santa Ana, CA		1.123	1.120
6 Los Angeles, CA		1.096	1.100
7 Marin/Napa/Solano, CA		1.154	1.165
8 Oakland/Berkeley, CA		1.152	1.154
9 San Francisco, CA		1.216	1.224
10 San Mateo, CA		1.210	1.216
11 Santa Clara, CA		1.204	1.209
12 Ventura, CA		1.105	1.100
13 Rest of California		1.053	1.053
14 Colorado		1.003	1.005
15 Connecticut		1.067	1.069
16 DC + MD/VA Suburbs		1.121	1.123
17 Delaware		1.024	1.021
18 Fort Lauderdale, FL		1.014	1.006
19 Miami, FL		1.017	1.011
20 Rest of Florida		0.973	0.971
21 Atlanta, GA		1.005	1.002
22 Rest of Georgia		0.940	0.940
23 Hawaii/Guam		1.075	1.077
24 Idaho		0.935	0.930
25 Chicago, IL		1.033	1.026
26 East St. Louis, IL		0.962	0.961
27 Suburban Chicago, IL		1.041	1.033
28 Rest of Illinois		0.944	0.944
29 Indiana		0.948	0.948
30 Iowa		0.929	0.933
31 Kansas		0.933	0.935
32 Kentucky		0.925	0.926
33 New Orleans, LA		0.983	0.986
34 Rest of Louisiana		0.930	0.935
35 Southern Maine		0.998	0.994
36 Rest of Maine		0.940	0.944
37 Baltimore/Surr. Cntys, MD		1.059	1.058
38 Rest of Maryland		1.024	1.025