

NEW YORK
state department of
HEALTH

Nirav R. Shah, M.D., M.P.H.
Commissioner

Sue Kelly
Executive Deputy Commissioner

March 4, 2013

Mr. Michael Melendez
Associate Regional Administrator
Department of Health & Human Services
Centers for Medicare & Medicaid Services
New York Regional Office
Division of Medicaid and Children's Health Operations
26 Federal Plaza - Room 37-100 North
New York, New York 10278

RE: SPA #12-36

Dear Mr. Melendez:

Enclosed for your approval is submittal #12-36, which is an amendment to this Department's State Plan under Title XIX (Medical Assistance).

The purpose of this State Plan Amendment is to request an exemption pursuant to 42 CFR 455.508(f) to the regulation requiring the State's Recovery Audit Contractors (RACs) not review claims older than three years.

Section 455.508(f) states, "The entity must not review claims that are older than 3 years from the date of the claim, unless it receives approval from the State."

New York State regulations (18 NYCRR Section 504.3) require providers "to prepare and to maintain contemporaneous records demonstrating its right to receive payment under the medical assistance program and to keep for a period of six years from the date the care, services or supplies were furnished, all records necessary to disclose the nature and extent of services furnished and all information regarding claims for payment submitted by, or on behalf of, the provider and to furnish such records and information, upon request, to the department, the Secretary of the United States Department of Health and Human Services, the Deputy Attorney General for Medicaid Fraud Control and the New York State Department of Health".

Effective January 1, 2013, we are requesting that CMS allow the State flexibility in meeting this requirement and are requesting an exception using the State Plan Amendment process for the following reasons:

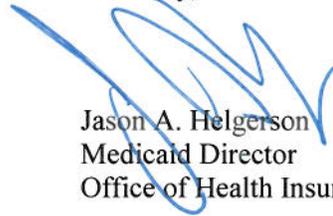
- 1) Claim specific detail may be present documenting an overpayment exists for periods beyond the three years specified in section 42 CFR 455.508(f);

- 2) A look-back period longer than three years is more consistent with Medicaid provider record retention requirements required by New York State regulatory agencies; and
- 3) A longer look-back period will allow for additional efficiencies for both the State and provider when a single effort can review and recover an identified overpayment rather than leveraging multiple entities to review and recover different time periods.

This exception shall only apply to reviews based on actual claim specific detail. Audits that require sampling and extrapolation will continue to be limited to the three-year look back period.

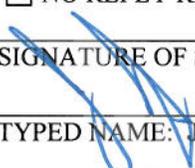
If you have any questions regarding this State Plan submission, please do not hesitate to contact John E. Ulberg, Jr., Medicaid Chief Financial Officer, Division of Finance and Rate Setting at (518) 474-6350.

Sincerely,



Jason A. Helgerson
Medicaid Director
Office of Health Insurance Programs

Enclosures

| | | | |
|---|--|---|-----------------------------|
| TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL FOR: HEALTH CARE FINANCING ADMINISTRATION | | 1. TRANSMITTAL NUMBER: 12-36 | 2. STATE New York |
| | | 3. PROGRAM IDENTIFICATION: TITLE XIX OF THE SOCIAL SECURITY ACT (MEDICAID) | |
| TO: REGIONAL ADMINISTRATOR HEALTH CARE FINANCING ADMINISTRATION DEPARTMENT OF HEALTH AND HUMAN SERVICES | | 4. PROPOSED EFFECTIVE DATE January 1, 2013 | |
| 5. TYPE OF PLAN MATERIAL (<i>Check One</i>): <input type="checkbox"/> NEW STATE PLAN <input type="checkbox"/> AMENDMENT TO BE CONSIDERED AS NEW PLAN <input checked="" type="checkbox"/> AMENDMENT COMPLETE BLOCKS 6 THRU 10 IF THIS IS AN AMENDMENT (<i>Separate Transmittal for each amendment</i>) | | | |
| 6. FEDERAL STATUTE/REGULATION CITATION: Section 1902(a)(42) of the Social Security Act & Section 42 CFR 455.508(f) | | 7. FEDERAL BUDGET IMPACT: a. FFY 01/01/12-09/30/13 \$ 0 b. FFY 10/01/13-09/30/14 \$ 0 | |
| 8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT: Page 36-4 | | 9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (<i>If Applicable</i>): | |
| 10. SUBJECT OF AMENDMENT: Exception from Medicaid RAC Three-Year Look Back Period (FMAP = 50%) | | | |
| 11. GOVERNOR'S REVIEW (<i>Check One</i>): <input checked="" type="checkbox"/> GOVERNOR'S OFFICE REPORTED NO COMMENT <input type="checkbox"/> OTHER, AS SPECIFIED: <input type="checkbox"/> COMMENTS OF GOVERNOR'S OFFICE ENCLOSED <input type="checkbox"/> NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL | | | |
| 12. SIGNATURE OF STATE AGENCY OFFICIAL:  | | 16. RETURN TO: New York State Department of Health Bureau of HCRA Oper & Financial Analysis 99 Washington Ave – One Commerce Plaza Suite 810 Albany, NY 12210 | |
| 13. TYPED NAME: Jason A. Helgerson | | | |
| 14. TITLE: Medicaid Director Department of Health | | | |
| 15. DATE SUBMITTED: March 4, 2013 | | | |
| FOR REGIONAL OFFICE USE ONLY | | | |
| 17. DATE RECEIVED: | | 18. DATE APPROVED: | |
| PLAN APPROVED – ONE COPY ATTACHED | | | |
| 19. EFFECTIVE DATE OF APPROVED MATERIAL: | | 20. SIGNATURE OF REGIONAL OFFICIAL: | |
| 21. TYPED NAME: | | 22. TITLE: | |
| 23. REMARKS: | | | |

Appendix I
2012 Title XIX State Plan
Fourth Quarter Amendment
Amended SPA Pages

Appendix II
2012 Title XIX State Plan
Fourth Quarter Amendment
Summary

SUMMARY
SPA #12-36

This State Plan Amendment proposes to request an exception to the three-year look back period for the Medicaid Recovery Audit Contractor (RAC) Program. The State is requesting the ability to grant a look back period for the Medicaid RAC up to six years, upon State approval of the RAC scenario for the following reasons: claim specific detail which may be present documenting an overpayment exists for periods beyond the three-years specified in Section 42 CFR 455.508(f); a look-back period longer than three years is more consistent with Medicaid provider record retention requirements required by New York State regulatory agencies; and a longer look-back period will allow for additional efficiencies for both the state and provider when a single effort can review and recover an identified overpayment rather than leveraging multiple entities to review and recover different time periods. This exception will only apply to reviews based on actual claim specific detail. Audits that require sampling and extrapolation will continue to be limited to the 3-year look back period.

Appendix III
2012 Title XIX State Plan
Fourth Quarter Amendment
Authorizing Provisions

achieving its participation goal and to respond to inquiries. Respondents are State Medicaid Agencies. The data is due April 1 of every year so States need to have the form and instructions as soon as possible in order to report timely. *Frequency*: Yearly; *Affected Public*: State, Tribal and Local governments; *Number of Respondents*: 56; *Total Annual Responses*: 112; *Total Annual Hours*: 1,568. (For policy questions regarding this collection contact Cindy Ruff at 410-786-5916. For all other issues call 410-786-1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web Site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov, or call the Reports Clearance Office on (410) 786-1326.

To be assured consideration, comments and recommendations for the proposed information collections must be received by the OMB desk officer at the address below, no later than 5 p.m. on October 12, 2010.

OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395-6974, E-mail: OIRA_submission@omb.eop.gov.

Dated: September 3, 2010.

Martique Jones,

Director, Regulations Development Division-B, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2010-22592 Filed 9-9-10; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

[Document Identifier: CMS-10207, CMS-10244, CMS-10343 and CMS-R-131]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare and Medicaid Services.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare and Medicaid Services (CMS) is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden

estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. Type of Information Collection Request: Extension of a currently approved collection; **Title of Information Collection:** Physician Self-Referral Exceptions for Electronic Prescribing and Electronic Health Records; **Use:** Section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) directed the Secretary to create an exception to the physician self-referral prohibition in section 1877 of the Social Security Act for certain arrangements in which a physician receives compensation in the form of items or services (not including cash or cash equivalents) ("nonmonetary remuneration") that is necessary and used solely to receive and transmit electronic prescription information. Also, CMS created a separate regulatory exception for certain arrangements involving the provision of nonmonetary remuneration in the form of electronic health records software or information technology and training services necessary and used predominantly to create, maintain, transmit, or receive electronic health records.

The conditions for both exceptions require that arrangements for the items and services provided must be set forth in a written agreement, be signed by the parties involved, specify the items or services being provided and the cost of those items or services, and cover all of the electronic prescribing and/or electronic health records technology to be provided by the donating entity. CMS would use the collected information for enforcement purposes; specifically, if we were investigating the financial relationships between the donors and the physicians to determine whether the provisions in the exceptions were met. **Form Number:** CMS-10207 (OMB#: 0938-1009); **Frequency:** Occasionally; **Affected Public:** Private Sector: Business or other for-profits and Not-for-profit institutions; **Number of Respondents:** 9,796; **Total Annual Responses:** 38,959; **Total Annual Hours:** 12,451.5. (For policy questions regarding this collection contact Kristin Bohl at 410-

786-8680. For all other issues call 410-786-1326.)

2. Type of Information Collection Request: Extension of a currently approved collection; **Title of Information Collection:** Medicaid State Program Integrity Assessment (SPIA); **Use:** Under the provisions of the Deficit Reduction Act (DRA) of 2005, the Congress directed CMS to establish the Medicaid Integrity Program (MIP), CMS' first national strategy to combat Medicaid fraud, waste, and abuse. CMS has two broad responsibilities under the MIP: (1) Reviewing the actions of individuals or entities providing services or furnishing items under Medicaid; conducting audits of claims submitted for payment; identifying overpayments; and educating providers and others on payment integrity and quality of care; and (2) Providing effective support and assistance to States to combat Medicaid fraud, waste, and abuse.

In order to fulfill the second of these requirements, CMS developed SPIA. CMS uses SPIA to collect data on State Medicaid program integrity activities, develop reports for each State based on these data, determine areas to provide States with technical support and assistance, and develop measures to assess States' performance. **Form Number:** CMS-10244 (OMB#: 0938-1033); **Frequency:** Annually; **Affected Public:** State, Local, or Tribal Governments; **Number of Respondents:** 56; **Total Annual Responses:** 56; **Total Annual Hours:** 1,400. (For policy questions regarding this collection contact Mary Jo Cook at 410-786-3231. For all other issues call 410-786-1326.)

3. Type of Information Collection Request: New collection; **Title of Information Collection:** State Plan Preprint for Medicaid Recovery Audit Contractors (RACs); **Use:** Under section 1902(a)(42)(B)(i) of the Social Security Act, States are required to establish programs to contract with one or more Medicaid RACs for the purpose of identifying underpayments and recouping overpayments under the State plan and any waiver of the State plan with respect to all services for which payment is made to any entity under such plan or waiver. Further, the statute requires States to establish programs to contract with Medicaid RACs in a manner consistent with State law, and generally in the same manner as the Secretary contracts with Medicare RACs.

State programs contracted with Medicaid RACs are not required to be fully operational until after December 31, 2010. States may submit, to CMS, a State Plan Amendment (SPA) attesting

that they will establish a Medicaid RAC program. States have broad discretion regarding the Medicaid RAC program design and the number of entities with which they elect to contract. Many States already have experience utilizing contingency-fee-based Third Party Liability recovery contractors. *Form Number:* CMS-10343 (OMB#: 0938-NEW); *Frequency:* Once; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 56; *Total Annual Responses:* 56; *Total Annual Hours:* 56. (For policy questions regarding this collection contact Mary Jo Cook at 410-786-3231 or Eva Tetteyfi at 410-786-3653. For all other issues call 410-786-1326.)

4. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Advance Beneficiary Notice of Noncoverage (ABN); *Use:* Under section 1879 of the Social Security Act, a physician, provider, practitioner, or supplier of items or services participating in the Medicare program, or taking a claim on assignment, may bill a Medicare beneficiary for items or services usually covered under Medicare, but denied in an individual case under one of the several statutory exclusions, if they inform the beneficiary, prior to furnishing the service, that Medicare is likely to deny payment. Sections 42 CFR 411.404(b) and (c), and 411.408(d)(2) and (f), require written notice be provided to inform beneficiaries in advance of potential liability for payment. *Form Number:* CMS-R-131 (OMB#: 0938-0566); *Frequency:* Reporting: Weekly, Monthly, Yearly, Biennially and Occasionally; *Affected Public:* Private Sector: Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 1,326,282 ; *Total Annual Responses:* 43,725,850; *Total Annual Hours:* 5,099,309. (For policy questions regarding this collection contact Evelyn Blaemire at 410-786-1803. For all other issues call 410-786-1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web Site at <http://www.cms.hhs.gov/PaperworkReductionActof1995>, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov, or call the Reports Clearance Office on (410) 786-1326.

In commenting on the proposed information collections please reference the document identifier or OMB control number. To be assured consideration,

comments and recommendations must be submitted in one of the following ways by *November 9, 2010*:

1. *Electronically.* You may submit your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number, Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: September 3, 2010.

Martique Jones,

Director, Regulations Development Division-B, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2010-22593 Filed 9-9-10; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-E-0041]

Determination of Regulatory Review Period for Purposes of Patent Extension; SAPHRIS

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for SAPHRIS and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Submit electronic comments to <http://www.regulations.gov>. Submit written petitions along with three copies and written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6222, Silver Spring, MD 20993-0002, 301-796-3602.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product SAPHRIS (asenapine). SAPHRIS is an atypical antipsychotic indicated for acute treatment of schizophrenia in adults and acute treatment of manic or mixed episodes associated with bipolar I disorder in adults. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for SAPHRIS (U.S. Patent No. 5,763,476) from NV Organon, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated March 3, 2010, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of SAPHRIS represented the first permitted commercial marketing or use of the product. Thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

Appendix IV
2012 Title XIX State Plan
Non-Institutional Services
Public Notice

MISCELLANEOUS NOTICES/HEARINGS

Notice of Abandoned Property Received by the State Comptroller

Pursuant to provisions of the Abandoned Property Law and related laws, the Office of the State Comptroller receives unclaimed monies and other property deemed abandoned. A list of the names and last known addresses of the entitled owners of this abandoned property is maintained by the office in accordance with Section 1401 of the Abandoned Property Law. Interested parties may inquire if they appear on the Abandoned Property Listing by contacting the Office of Unclaimed Funds, Monday through Friday from 8:00 a.m. to 4:30 p.m., at:

1-800-221-9311
or visit our web site at:
www.osc.state.ny.us

Claims for abandoned property must be filed with the New York State Comptroller's Office of Unclaimed Funds as provided in Section 1406 of the Abandoned Property Law. For further information contact: Office of the State Comptroller, Office of Unclaimed Funds, 110 State St., Albany, NY 12236.

PUBLIC NOTICE

Division of Criminal Justice Services
Commission On Forensic Science

Pursuant to Public Officers Law section 104, the Division of Criminal Justice Services gives notice of a meeting of the New York State Commission on Forensic Science to be held on:

Date: Wednesday, Dec. 19, 2012
Time: 8:30 a.m.
Place: Empire State Development Corporation (ESDC)
633 3rd Ave.
37th Fl.
New York, NY

Identification and sign-in are required at this location. For further information, or if you need a reasonable accommodation to attend this meeting, contact Louis Stellato, Division of Criminal Justice Services, Office of Forensic Services, Four Tower Place, Albany, NY 12203, (518) 457-1901.

PUBLIC NOTICE

Department of Health

Pursuant to 42 CFR Section 447.205, the Department of Health hereby gives public notice of the following:

The Department of Health proposes to amend the Title XIX (Medicaid) State Plan for all services to comply with enacted statutory provisions. The following changes are proposed:

All Services

Under Section 6411 of the Affordable Care Act (P.L. 111-148), Expansion of the Recovery Audit Contractor (RAC) Program, which amends section 1902(a)(42) of the Social Security Act, states were required to establish programs to contract with RACs to audit payments to Medicaid providers by December 31, 2010 and fully implement such by April 1, 2011.

New York State is seeking to request an exception to the three-year look back period for the Medicaid RAC program as defined by State regulation, and give the State the ability to grant a look back period for the Medicaid RAC up to six years. The longer look back period will allow the State to review claim specific detail for any overpayments; is more consistent with Medicaid provider record retention requirements required by State regulatory agencies; and allow for additional efficiencies for both the State and provider when a single effort can review and recover an identified overpayment rather than leveraging multiple entities to review and recover different time periods.

This exception shall be effective January 1, 2013, and only apply to reviews based on actual claim specific detail. Audits that require sampling and extrapolation will continue to be limited to the three-year look back period.

There is no additional estimated annual change to gross Medicaid expenditures as a result of the clarifying proposed amendments.

The public is invited to review and comment on this proposed State Plan Amendment. Copies of which will be available for public review on the Department's website at http://www.health.ny.gov/regulations/state_plans/status.

Copies of the proposed State Plan Amendments will be on file in each local (county) social services district and available for public review.

For the New York City district, copies will be available at the following places:

New York County
250 Church Street
New York, New York 10018

Queens County, Queens Center
3220 Northern Boulevard
Long Island City, New York 11101

Kings County, Fulton Center
114 Willoughby Street
Brooklyn, New York 11201

Bronx County, Tremont Center
1916 Monterey Avenue
Bronx, New York 10457

Richmond County, Richmond Center
95 Central Avenue, St. George
Staten Island, New York 10301

The public is invited to review and comment on this proposed State Plan Amendment.

For further information and to review and comment, please contact: Department of Health, Bureau of HCRA Operations & Financial Analysis, 99 Washington Ave., One Commerce Plaza, Suite 810, Albany, NY 12210, (518) 474-1673, (518) 473-8825 (FAX), e-mail: spa_inquiries@health.state.ny.us