plan to meet its ongoing responsibilities to ensure compliance). The names of those covered entities which submit a certification, or an alternate mechanism approved by OPA, will be listed on the OPA Web site for the convenience of participating drug manufacturers and wholesaler distributors.

In addition, any covered entity that has opted to utilize any pharmacy arrangement described in (2) must specify which arrangement or combination of arrangements it is utilizing and the names of any pharmacies participating when registering. Covered entities seeking to materially change this arrangement that entail changes in the covered entity database should notify OPA of any such proposed changes and be aware that some changes may require advanced notice to manufacturers and wholesalers as part of quarterly updates to the database.

In order to ensure accuracy, integrity and transparency, the OPA may conduct a recertification process periodically (most likely annually) where covered entities affirmatively certify as to their ongoing compliance with 340B requirements. It is currently expected that the annual process would include certification by a duly authorized official: (1) That all information listed on the database for that covered entity is complete, accurate, and correct; (2) that the covered entity met the 340B eligibility requirements throughout the prior year and continues to do so; (3) that any contract pharmacy arrangement was actually performed in accordance with specified requirements including, but not limited to, that the covered entity obtained sufficient information from the contractor to ensure compliance with applicable policy and legal requirements; and (4) the methodology utilized to ensure compliance (*e.g.* through independent audit or other mechanism).

(6) Anti-Kickback Statute

Contract pharmacies and covered entities should be aware of the potential for civil or criminal penalties if the contract pharmacy violates Federal or State law. In negotiating and executing a contract pharmacy service agreement pursuant to these guidelines, contract pharmacies and covered entities should be aware of and take into consideration the provisions of the Medicare and Medicaid anti-kickback statute, 42 U.S.C. 1320a–7b(b).

D. Appendix—Suggested Contract Provisions

The following suggested contract provisions are included for illustrative purposes and are not intended to be comprehensive, exhaustive or required. They offer sample provisions for consideration, but are not intended to be used as the complete terms of the contract. Given the variances among many jurisdictions and among the numerous types of covered entities, HRSA has decided at this time not to include a complete model contract in this notice.

(1) "The covered entity owns covered drugs and arranges to be billed directly for such drugs. The pharmacy will compare all shipments received to the orders and inform the covered entity of any discrepancy within five (5) business days of receipt. The covered entity will make timely payments for such drugs delivered to the pharmacy."

(2) "The covered entity will verify, using the contract pharmacy's (readily retrievable) customary business records, that a tracking system exists which will ensure that drugs purchased under the 340B Drug Pricing Program are not diverted to individuals who are not patients of the covered entity. Such records can include: Prescription files, velocity reports, and records of ordering and receipt. These records will be maintained for the period of time required by State law and regulations."

(3) "Prior to the contract pharmacy providing pharmacy services pursuant to this agreement, the covered entity will have the opportunity, upon reasonable notice and during business hours, to examine the tracking system. For example, such a tracking system may include quarterly sample comparisons of eligible patient prescriptions to the dispensing records and a six (6) month comparison of 340B drug purchasing and dispensing records as is routinely done in other reconciliation procedures. The contract pharmacy will permit the covered entity or its duly authorized representatives to have reasonable access to contract pharmacy's facilities and records during the term of this agreement in order to make periodic checks regarding the efficacy of such tracking systems. The contract pharmacy agrees to make any and all adjustments to the tracking system which the covered entity advises are reasonably necessary to prevent diversion of covered drugs to individuals who are not patients of the covered entity."

(4) "The pharmacy will dispense covered drugs only in the following circumstances: (a) Upon presentation of a prescription bearing the covered entity's name, the eligible patient's name, a designation that the patient is an eligible patient of the covered entity, and the signature of a legally qualified health care provider affiliated with the covered entity; or (b) receipt of a prescription ordered by telephone or other means of electronic transmission that is permitted by State or local law on behalf of an eligible patient by a legally qualified health care provider affiliated with the covered entity who states that the prescription is for an eligible patient. The covered entity will furnish a list to the pharmacy of all such qualified health care prescribers and will update the list of prescribers to reflect any changes. If a contract pharmacy is found to have violated the drug diversion prohibition, the contract pharmacy will pay the covered entity the amount of the discount in question so that the covered entity can reimburse the manufacturer."

Dated: March 2, 2010.

Mary K. Wakefield,

Administrator.

[FR Doc. 2010–4755 Filed 3–4–10; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–3070 and CMS–416]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services, 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 function; (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: Intermediate Care Facility (ICF) for the Mentally Retarded (MR) or Persons with Related Conditions Survey Report Form and Supporting Regulations at 42 CFR 442.30, 483.410, 483.420, 483.440, 483.450 and 483.460; *Use:* This survey form is needed to ensure ICF/MR provider and client characteristics are available and updated annually for the Federal government's Online Survey Certification and Reporting (OSCAR) system. It is required for the provider to fill out at the time of the annual recertification or initial certification survey conducted by the State Medicaid agency. The team leader for the State survey team must review and approve the completed form before completion of the survey. The State Medicaid survey agency is responsible for transferring the 3070 information into OSCAR. *Form Number:* CMS–3070 (OMB#: 0938–0062); *Frequency:* Reporting—Yearly; *Affected Public:* Private Sector: Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 6,437; *Total Annual Responses:* 6,437; *Total Annual Hours:* 19,311. (For policy questions regarding this collection contact Kelley Tinsley at 410–786–6664. For all other issues call 410–786–1326.)

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Annual Early and Periodic Screening, Diagnostic and Treatment (EPSDT) Services Participation Report; *Form Number:* CMS–416 (OMB#: 0938–0354); *Use:* States are required to submit an annual report on the provision of EPSDT services pursuant to section 1902(a)(43)(D) of the Social Security Act. These reports provide CMS with data necessary to assess the effectiveness of State EPSDT programs, to determine a State's results in 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:* 56; *Total Annual Hours:* 504. (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 *April 5, 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: February 24, 2010.

Michelle Shortt,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2010–4313 Filed 3–4–10; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301/496–7057; fax: 301/402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Monoclonal Antibody to Mouse Toll-Like Receptor 3 (TLR3) Extracellular Domain

Description of Invention: The best available antibody for labeling cells expressing mouse TLR3 is now available for licensing. It is a rat IgG2a monoclonal antibody that was generated to the extracellular domain of mouse TLR3 and specifically binds mouse TLR3 in permeabilized cells. TLR3 is located in endosomes and recognizes double-stranded RNA, a molecular signature of many viruses. This antibody would be of interest to anyone studying TLR3 distribution and localization in studies related to innate immunity and dendritic cell function.

Applications:

- Fluorescence-Activated Cell Sorting (FACS).
- Immunofluorescence.
- Immunocytochemistry.

Inventors: David M. Segal, Yan Wang, Ivett Jelinek (NCI).

Related Publication: Unpublished.

Patent Status: HHS Reference No. E–038–2010/0—Research Tool. Patent protection is not being pursued for this technology.

Licensing Status: This technology is available as a research tool (hybridoma) under a Biological Materials License.

Licensing Contact: Steve Standley, Ph.D.; 301–435–4074; *sstand@od.nih.gov.*

Haptoglobin for Control of the Blood Pressure Response to Plasma Free Hemoglobin

Description of Invention: Release of hemoglobin into the blood is a central pathophysiologic event contributing to morbidity and mortality in chronic and acute hemolytic anemias and severe malaria. These toxicities arise from hemoglobin-related scavenging of nitric oxide, a blood vessel vasodilator, and peroxidative chain reactions that lead to damage of the surrounding tissues. Animal models have demonstrated both an attenuation of the hypertensive response due to nitric oxide scavenging and a prevention of peroxidative toxicity. Compartmentalization of hemoglobin, rather than short-lived nitric oxide-based drugs, may represent a new therapeutic paradigm in countering the pathophysiological side effects associated with free hemoglobin.

This technology identifies haptoglobin and haptoglobin mimetics as potential therapeutics for high blood pressure and intravascular toxicity due to release of hemoglobin from red blood cells. It provides a novel process in which free hemoglobin is compartmentalized within the haptoglobin molecule. Therapeutic proof-of-principle has been demonstrated for this technology in dog and guinea pig models.

Potential Applications and Advantages: