

The proposed Consent Order remedies the merger's anticompetitive effects by requiring that Immunex license certain patents to Regeneron, given Regeneron the freedom of operation necessary to bring its IL-1 Trap product to the market and compete against Amgen in this market.

The purpose of this analysis is to facilitate public comment on the proposed Consent Order, and it is not intended to constitute an official interpretation of the proposed Consent Order or to modify its terms in any way.

By direction of the Commission.

Donald S. Clark,
Secretary.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Agency Information Collection Activities; Proposed Collections; Comment Request

The Department of Health and Human Services, Office of the Secretary will periodically publish summaries of proposed information collections projects and solicit public comments in compliance with the requirements of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995. To request more information on the project or to obtain a copy of the information collection plans and instruments, call the OS Reports Clearance Officer on (202) 690-6207.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

1. *HHS Acquisition Regulation (HHSAR) Part 342—Contract Administration—0990-0131—Extension with no change*—HHSAR 342.7103 requires reporting information when a cost overrun is anticipated. The information is used to determine if a proposed overrun is reasonable.

Respondents: State or local governments, business, or other for-profit, non-profit institutions, small business; *Number of respondents:* 215; *Average burden per response:* 20 hours; *Total burden:* 4,300 hours.

2. *HHS Acquisition Regulations (HHSAR) Part 333 Disputes and Appeals—0990-0133—Extension with no change*—The Litigation and Claims clause is needed to inform the government of actions filed against government contracts. *Respondents:* State or local governments, business or other for-profit institutions, small business; *Number of respondents:* 86; *Average burden per response:* 30 minutes; *Total burden:* 43 hours.

3. *HHS Acquisition Regulation (HHSAR) Part 332—Contract Financing—0990-0134—Extension with no change*—The requirements of HHSAR Part 332 are needed to ascertain costs associated with certain contracts so as to timely pay contractors. *Respondents:* State or local governments, small businesses; *Number of respondents:* 226; *Average burden per response:* one hour; *Total burden:* 226 hours.

4. *HHS Acquisition Regulation (HHSAR) Part 324—Protection of Privacy and Freedom of Information—0990-0136—Extension with no change*—The confidentiality of information requirements are needed to prevent improper disclosure of confidential data. *Respondents:* State of local governments, business or other for-profit, non-profit institutions, small businesses; *Number of respondents:* 638; *Average burden per response:* 8 hours; *Total burden:* 5,104 hours.

5. *HHS Acquisition Regulation (HHSAR) Part 316—Types of Contracts—0990-0138—Extension with no change*—The negotiated Overhead Rate—Fixed clause is needed since fixed rates are authorized by OMB Circular and a clause is not provided in the Federal Acquisition Regulation (FAR). *Respondents:* non-profit institutions; *Number of respondents:* 520; *Average burden per response:* 10 hours; *Total burden:* 5,200 hours.

6. *Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments—0990-0169—Extension with no change*—Pre-award, post-award, and subsequent reporting and recordkeeping requirements are necessary to award, monitor, close out and manage grant programs, ensure minimum fiscal control and accountability for Federal funds and deter fraud, waste and abuse. *Respondents:* State and local governments; *Number of respondents:*

4,000; *Average burden per response:* 70 hours; *Total burden:* 280,000 hours.

7. *HHS Acquisition Regulation (HHSAR) Part 370—Special Programs Affecting Acquisition—0990-0129—Extension with no change*—Establishes requirements for the accessibility of meetings, conferences, and seminars to persons with disabilities; establishes requirements for Indian Preference in employment, training and subcontracting opportunities. *Respondents:* State or local governments, businesses or other for-profit, non-profit institutions, small businesses; *Burden Information about Accessibility of Meetings—Annual number of respondents:* 335; *Average burden per response:* 10 hours; *Total annual number of respondents:* 932; *Average burden per response:* 8 hours; *Total annual burden:* 7,456 hours—*Total Burden:* 10,806 hours.

8. *HHS Acquisition Regulation (HHSAR) Part 352—Solicitation Provisions and Contract Clauses—0990-0130—Extension with no change*—The Key Personnel clause in HHSAR 352.27-5 requires contractors to obtain approval before substituting key personnel which are specified in the contract. *Respondents:* State or local governments, businesses or other for-profit, non-profit institutions, small businesses; *Total number of respondents:* 1,921; *Average burden per response:* 2 hours; *Total burden:* 3,842 hours.

Send comments to Cynthia Agents Bauer, OS Reports Clearance Officer, Room 503H, Humphrey Building, 200 Independence Avenue, SW., Washington DC, 20201. Written comments should be received within 60 days of this notice.

Dated: July 16, 2002.

Kerry Weems,

Deputy Assistant Secretary, Budget.

[FR Doc. 02-18622 Filed 7-23-02; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Request for Measures of Patients' Hospital Care Experiences

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Notice of Request for measures.

SUMMARY: The Agency for Healthcare Research and Quality (AHRQ) is soliciting the submission of instruments measuring patients' experience with the

quality of hospital care from researchers, stakeholders and other interested parties. This initiative is in response to the priority established by the Acting Director of AHRQ and the Administrator of the Centers for Medicare & Medicaid Services (CMS), which is to support the development of a standard that would be used nationwide. While CAHPS®, funded by AHRQ, has been accepted as the industry standard for measuring consumers' experiences within the health care system, it does not address patients' experiences within the acute care setting. In response to this need, AHRQ will initiate the process of developing a public domain instrument by reviewing existing instruments that capture the patients' hospital experiences.

DATES: Please submit instruments and supporting information by September 23, 2002. AHRQ will not respond individually to submitters, but will consider all submitted instruments and publicly report the results of the review of the submissions in aggregate.

ADDRESSES: Submissions should include a brief cover letter, a copy of the instrument for consideration and supporting information as specified under Submission Criteria, below. Submissions may be in the form of a letter or e-mail, preferably with an electronic file in a standard word processing format on a 3½-inch floppy disk or as an e-mail attachment. Responses to this request should be submitted to: Charles Darby, Agency for Healthcare Research and Quality, 6011 Executive Blvd., Suite 200, Rockville, MD 20852, Phone: (301) 594-2050, Fax: (301) 594-2155, E-mail: cdarby@ahrq.gov.

To facilitate handling of submissions, please include full information about the instrument developer or contact: (a) name, (b) title, (c) organization, (d) mailing address, (e) telephone number, (f) fax number and (g) e-mail address. Also, please submit a copy of the instrument, evidence that it meets the criteria below, *i.e.*, citation of a peer-reviewed journal article pertaining to the instrument to include the title of the article, author(s), publication year, journal name, volume, issue, and page numbers where article appears and or other applicable evidence. Submitters must also provide a statement of willingness to grant to AHRQ the right to use and authorize others to use submitted measures and their documentation as part of a CAHPS®-trademarked instrument. This CAHPS® instrument for patient assessment of hospital care will be made publicly

available, free of charge. Please do not use acronyms. Electronic submissions are encouraged.

FOR FURTHER INFORMATION CONTACT:

Charles Darby, Center for quality Improvement and Patient Safety, Agency for Healthcare Research and Quality, 6011 Executive Blvd., Suite 200, Rockville, MD 20852; Phone: (301) 594-2050; Fax: (301) 594-2155, e-mail: cdarby@ahrq.gov.

Submission Criteria

Instruments submitted should focus on acute, inpatient stays for medical, surgical care, OB/GYN and/or pediatric care. Measures submitted must meet these criteria to be considered: capture the patients' experience of care in acute care and/or hospital settings; demonstrate a high degree of reliability and validity; and have been used widely, not just in one or two research studies or local hospital settings. Submitters willingness to grant to AHRQ the right to use and authorize others to use the instrument means that the CAHPS® trademark will be applied to a new instrument combining the best features of all the submissions as well as any ideas that may develop from reviewing them, to ensure free access to the instrument, and free access to the instrument's supportive/administrative information. AHRQ, in collaboration with CAHPS grantees, will evaluate all submitted instruments and select one or more either in whole or in part for testing and, if required, additional modification. AHRQ will assume responsibility for the final measure set as well as any future modifications to the instrument.

The finalized instrument will bear the CAHPS® trademark and it will be made freely available for use by all interested parties. However, as a matter of quality control, there will be warnings that the CAHPS® identification may not be used if any changes are made to the instrument or final measure set without review and permission of the agency. Each submission should include the following information: the name of the instrument, whether the instrument is disease or condition specific, domain, language(s) the instrument is available in, evidence of cultural/cross group comparability, if any, instrument reliability (internal consistency, test-retest, etc.) validity (content, construct, criterion-related), response rates, methods and results of cognitive testing and field-testing and description of sampling strategies and data collection protocols, including such elements as mode of administration, use of advance letters, timing and frequencies of

contacts. In addition, a list of hospitals in which the instrument has been fielded or counts of the number of hospitals by state or region, in which the survey has been and/or is being used should also be included in the submission materials. Submission of copies of existing report formats developed to disclose findings to consumers and providers is desirable, but not required. Additionally, information about existing database(s) for the instrument(s) submitted is helpful, but not required for submission. Evidence of the criteria should be demonstrated through submission of peer-reviewed journal article(s) or through the best evidence available at the time of submission.

SUPPLEMENTARY INFORMATION:

Background

AHRQ is a leader in developing and testing instruments for measuring consumer experience within the healthcare system of the United States as evidenced by the development of CAHPS®, formerly the Consumer Assessment of Health Plans, which provides information on health plan quality to consumers and purchasers alike. While CAHPS® is highly regarded within the industry and provides valuable information; it does not address patients' experience within an acute care setting. Standardization of measures is the basis for the development of the CAHPS® system, and is essential for meaningful comparison of performance of hospitals and acute care health systems. Use of a standardized measure of patient experience in hospital settings provides several benefits including: comparable information across hospitals for the public about the quality of care from the patient's perspective; data-based recommendations for quality improvement efforts and a data base to stimulate research in this area.

Leaders in the health care sector have called for a response to these pressing needs. In "Crossing the Quality Chasm," the National Institute of Medicine (IOM) established patient-centered care as one of the industry's six aims for quality improvement. The dimensions of patient-centered care include: respect for patients' values, preferences, and expressed needs; coordination and integration of care; information, communication, and education; physical comfort; emotional support, *i.e.*, relieving fear and anxiety; involvement of family and friends; continuity and transition; and access to care (2001).

The measurement of these dimensions will require a standardized instrument that produces reliable and valid results.

Furthermore, the National Quality Forum (NQF) has cited the need for further research and development of suitable performance measures to evaluate and improve the quality of care in the hospital setting. Among the many priorities cited by the NQF in this area, the need to measure patient experiences with inpatient care is crucial.

In an effect to address the concerns of the industry, the Acting Director of AHRQ and the Administrator of the Centers for Medicare & Medicaid Services (CMS) have established a priority to develop a standard for measuring and the public reporting of patient experiences in the acute care setting.

AHRQ, through a collaborative process with CMS and other Federal agencies, as well as other stakeholders, has initiated the process for this project. The steps to advance this initiative include:

- *Stakeholder Meetings:* A series of public meetings will be held to identify the issues, concerns and interests of the healthcare community. Summaries of all meetings will be posted on the AHRQ Website: <http://www.ahrq.gov/qual/cahpsix.htm>.

- *Sponsorship:* Identify potential sponsors who will fund, assist in development and periodic revisions, and ultimately help support the process for implementing and maintaining this standardized instrument.

- *Research Plan:* The process by which measures will be defined and applicable instruments identified. Instruments submitted will be evaluated to determine if they meet the measurement needs and to identify whether additional measure development is required. Once consensus among AHRQ and the CAHPS Grantees on the instrument is achieved, and the instrument testing is concluded, the resulting work will be readily available free of charge to all prospective users.

- *Implementation Plan:* A description of the recommended or required process to implement the standardized instrument will also be readily available including information related to data collection, analysis, and public reporting.

Dated: July 18, 2002.

Carolyn M. Clancy,
Acting Director.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention (CDC)

Citizens Advisory Committee on Public Health Service Activities and Research at Department of Energy Sites: Notice of Charter Renewal

This gives notice under the Federal Advisory Committee Act (Pub. L. 92-463) of October 6, 1972, that the Citizens Advisory Committee on Public Health Service Activities and Research at Department of Energy Sites of the Centers for Disease Control and Prevention, Department of Health and Human Services, has been renewed for a 2-year period extending through July 7, 2004.

For further information, contact Burma Burch, CDC/ATSDR Committee Management Officer, Centers for Disease Control and Prevention of the Department of Health and Human Services, 1600 Clifton Road, NE., MS E72, Atlanta, Georgia 30333. Telephone (404) 498-0090, or fax (404) 498-0011.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: July 18, 2002.

John Burckhardt,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

[Document Identifier: CMS-10064]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare and Medicaid Services, DHHS.

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) (formerly known as the Health Care Financing Administration (HCFA)), 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 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.

Type of Information Collection Request: Extension of a currently approved collection; *Title of Information Collection:* Minimum Data Set (MDS) for Swing Bed Hospitals and Supporting Regulations in 42 CFR, Sections 413.337 and 483.20; *Form No.:* CMS-10064 (OMB# 0938-0872); *Use:* We are requesting re-approval of resident assessment information that swing bed hospitals are required to submit as described at 42 CFR 483.20 in the manner necessary to administer the payment rate methodology described in 42 CFR 413.337; *Frequency:* Other: Days 5, 14, 30, 60 & 90 of stay; *Affected Public:* Not-for-Profit Institutions, and State, Local or Tribal Government; *Number of Respondents:* 1,250; *Total Annual Responses:* 156,480; *Total Annual Hours:* 132,360.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS's Web site address at <http://www.hcfa.gov/regs/prdact95.htm>, or e-mail your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786-1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the CMS Paperwork Clearance Officer designated at the following address: CMS, Office of Information Services, Security and Standards Group, Division of CMS Enterprise Standards, Attention: Dawn Willingham, CMS-10064, Room N2-14-26, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.