

more of the acute inpatient psychiatric beds in each of the affected markets.

The presumption of anticompetitive harm created by the steep increases in market concentration is further supported by evidence of the intense rivalry between UHS- and PSI-owned facilities that would be eliminated by the proposed acquisition. In each of the local markets, consumers have benefitted from the head-to-head competition in the form of lower health care costs, higher quality of care, and improved service offerings. Left unremedied, the proposed acquisition likely would cause anticompetitive harm by enabling UHS to profit by unilaterally raising the reimbursement rates negotiated with commercial health plans. These costs are ultimately passed on to consumers in the form of higher premiums, co-pays, and other out-of-pocket costs. The loss of competition also reduces UHS's incentive to improve quality and provide better service.

New entry is unlikely to deter or counteract the anticompetitive effects of the proposed acquisition. Among other entry barriers, regulatory requirements pose substantial barriers to entrants attempting to establish new psychiatric facilities or to expand their offerings in the relevant markets. In particular, Delaware and Puerto Rico require Certificates of Need in order to enter or significantly expand the number of beds provided in the market. The availability of suitable land, local zoning regulations, and Medicare and Medicaid certifications also impact significantly the ability of firms to enter or expand. As a result, new entry sufficient to achieve a significant market impact is unlikely to occur in a timely manner in these markets.

The Proposed Consent Agreement

The proposed Consent Agreement wholly remedies the anticompetitive effects of the acquisition by requiring the divestiture of all of the PSI or UHS assets to a Commission-approved buyer (or buyers) within six months of the date the Consent Agreement becomes final in Delaware and Las Vegas, and within nine months in Puerto Rico. Specifically, the proposed Consent Agreement requires the divestiture of four facilities that provide acute inpatient psychiatric care, as well as related outpatient clinics, contracts, commercial trade names, and real property, in the three geographic markets. See Appendix A for a complete list of the divestiture assets. Each psychiatric facility and its associated clinics to be divested in Delaware and Puerto Rico is a stand-alone business, and includes all of the assets necessary

for a Commission-approved buyer to independently and effectively operate each facility. The two facilities in Las Vegas are closely related and complementary businesses and were jointly managed within PSI; as such, the two facilities together constitute a stand-alone business, and include all of the assets necessary for a Commission-approved buyer to independently and effectively operate the business.

The proposed Consent Agreement contains several provisions designed to ensure that the divestitures are successful. First, the Commission will evaluate the suitability of possible purchasers of the divested assets to ensure that the competitive environment that would have existed but for the transaction is replicated by the required divestitures. If UHS fails to divest the assets within the required time period to a Commission-approved buyer, the Consent Agreement permits the Commission to appoint a trustee to divest the assets. Second, UHS is required to provide transitional services to the Commission-approved buyer. These services will facilitate a smooth transition of the assets to the acquirer, and ensure continued and uninterrupted operation of the assets during the transition. Third, the Consent Agreement requires UHS to remove any contractual impediments that may deter the current managers of the facilities to be divested from accepting offers of employment from any Commission-approved acquirer and to obtain all consents necessary to transfer the required assets. Finally, to ensure that the Commission will have an opportunity to review any future attempt by UHS to acquire any acute inpatient psychiatric services provider in any of the three geographic markets at issue, the proposed Consent Agreement contains a ten-year prior notice provision.

The Hold Separate Order requires the parties to maintain the viability of the divestiture assets as competitive operations until each facility is transferred to a Commission-approved buyer. Specifically, the parties must maintain the confidentiality of sensitive business information, and take all actions necessary to prevent the destruction or wasting of the divestiture assets. After UHS acquires PSI, the Hold Separate Order requires that UHS separately hold and maintain the divestiture assets and appoint a Hold Separate Manager to operate these assets pending their divestiture.

The sole purpose of this analysis is to facilitate public comment on the Consent Agreement. This analysis does not constitute an official interpretation

of the Consent Agreement or 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

Renewal of Charter for the Secretary's Advisory Committee on Human Research Protections

AGENCY: Department of Health and Human Services, Office of the Secretary, Office of the Assistant Secretary for Health.

ACTION: Notice.

SUMMARY: As stipulated by the Federal Advisory Committee Act, as amended (5 U.S.C. App), the U.S. Department of Health and Human Services is hereby announcing renewal of the charter for the Secretary's Advisory Committee on Human Research Protections (SACHRP).

FOR FURTHER INFORMATION CONTACT: Jerry Menikoff, M.D., J.D., Director, Office for Human Research Protections or Julia Gorey, J.D., Executive Director, SACHRP; U.S. Department of Health and Human Services, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852; Telephone: (240) 453-6900; Fax: (240) 453-6909; e-mail address: julia.gorey@hhs.gov.

SUPPLEMENTARY INFORMATION: SACHRP was established in October 2002. The Committee was established to enhance and expand the focus of the former National Human Research Protections Advisory Committee (NHRPAC), which was terminated in August 2002. SACHRP provides expert advice and recommendations to the Secretary, through the Assistant Secretary for Health, on the conduct of research involving human subjects with particular emphasis on special populations, such as neonates and children, prisoners, and the decisionally impaired; pregnant women, embryos, and fetuses; individuals and populations in international studies; populations in which there are individually identifiable samples, data, or information; and investigator conflicts of interest.

Since SACHRP was established, renewal of the Committee charter has been carried out at the appropriate intervals as stipulated by FACA. The previous Committee charter was scheduled to expire on October 1, 2010. On October 1, 2010, the Secretary of

Health and Human Services approved for the Committee charter to be renewed. The new charter was effected and filed with the appropriate Congressional offices and Library of Congress on October 1, 2010. Renewal of the SACHRP charter provides authorization for the Committee to operate until October 1, 2012.

A copy of the Committee charter is available on the SACHRP Web site at <http://www.hhs.gov/ohrp/sachrp/charter.htm>. A copy of the Committee charter also can be obtained by accessing the FACA database that is maintained by the Committee Management Secretariat under the General Services Administration. The Web site address for the FACA database is <http://fido.gov/facadatabase>.

Dated: November 16, 2010.

Jerry Menikoff,

Director, Office for Human Research Protections, and Executive Secretary, Secretary's Advisory Committee on Human Research Protections.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Renewal of Charter for the Advisory Committee on Blood Safety and Availability

AGENCY: Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: As stipulated by the Federal Advisory Committee Act, as amended (5 U.S.C. App), the U.S. Department of Health and Human Services is hereby announcing renewal of the charter for the Advisory Committee on Blood Safety and Availability (ACBSA).

FOR FURTHER INFORMATION CONTACT: Jerry Holmberg, PhD; Senior Advisor for Blood Policy and Executive Secretary, Advisory Committee on Blood Safety and Availability; Department of Health and Human Services; 1101 Wootton Parkway; Tower Building, Suite 250; Rockville, MD 20852; Telephone: (240) 453-8803; Fax: (240) 453-8456; E-mail address: acbsa@hhs.gov.

SUPPLEMENTARY INFORMATION: ACBSA was established in 1996. The Committee provides advice and guidance to the Secretary, through the Assistant Secretary for Health, on a range of blood safety issues that encompass broad public health and societal implications that cannot be resolved through analysis of scientific data alone. The range of

issues on which the Committee is tasked to provide advice and guidance includes, but is not limited to: (1) Definition of public health parameters around safety and availability of the blood and blood products; (2) broad public health, ethical, and legal issues related to transfusion and transplantation safety; and (3) implications for safety and availability of various economic factors affecting product cost and supply.

Since the ACBSA was established, renewal of the Committee charter has been carried out at the appropriate intervals as stipulated by FACA. The previous Committee charter was scheduled to expire on October 9, 2010. On October 8, 2010, the Secretary of Health and Human Services approved for the Committee charter to be renewed. The new charter was effected and filed with the appropriate Congressional offices and Library of Congress on October 9, 2010. Renewal of the ACBSA charter provides authorization for the Committee to operate until October 9, 2012.

A copy of the Committee charter is available on the ACBSA Web site at <http://www.hhs.gov/ash/bloodsafety/>. A copy of the Committee charter also can be obtained by accessing the FACA database that is maintained by the Committee Management Secretariat under the General Services Administration. The Web site address for the FACA database is <http://fido.gov/facadatabase>.

Dated: November 17, 2010.

Jerry A. Holmberg,

Senior Advisor for Blood Policy, Executive Secretary, Advisory Committee on Blood Safety and Availability.

[FR Doc. 2010-29518 Filed 11-22-10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0422]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Information From United States Firms and Processors That Export to the European Community

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of

information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by December 23, 2010.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or e-mailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0320. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-3793.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Information From United States Firms and Processors That Export to the European Community (OMB Control Number 0910-0320)—Revision

The European Community (EC) is a group of 27 European countries that have agreed to harmonize their commodity requirements to facilitate commerce among member States. EC legislation for intra-EC trade has been extended to trade with non-EC countries, including the United States. For certain food products, including those listed in this document, EC legislation requires assurances from the responsible authority of the country of origin that the processor of the food is in compliance with applicable regulatory requirements. The European Commission, the executive branch of the EC, requires countries trading with any of the EC member countries to provide lists of firms and processors approved to export certain animal-derived commodities to the EC. As stated in the notice published in the *Federal Register* of April 4, 1996 (61 FR 15077), FDA established a list of U.S. firms and processors that intended to export shell eggs, dairy products, and game meat and game meat products to the EC.

Although the 1996 *Federal Register* notice did not include on the list firms and processors exporting raw, bulk collagen, and gelatin intended for