DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committee; Renewals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the renewal of certain FDA advisory committees by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the charters of the committees listed below for an additional 2 years beyond charter expiration date. The new charters will be in effect until the dates of expiration listed below. This notice is issued under the Federal Advisory Committee Act of October 6, 1972 (Public Law 92–463 (5 U.S.C. app. 2)).

DATES: Authority for these committees will expire on the dates indicated below unless the Commissioner formally determines that renewal is in the public interest.

Name of committee	Date of expiration
Technical Electronic Product Radiation Safety Standards Committee	December 24, 2000
Antiviral Drugs Advisory Committee	February 15, 2001
National Mammography Quality Assurance Advisory Committee	July 6, 2001
Nonprescription Drugs Advisory Committee	August 27, 2001

FOR FURTHER INFORMATION CONTACT: Donna M. Combs, Committee Management Office (HFA–306), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4820.

Dated: November 3, 1999.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 99–29353 Filed 11–9–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Clinical Chemistry and Clinical Toxicology Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Clinical Chemistry and Clinical Toxicology Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues as provided in the Federal Food, Drug, and Cosmetic Act.

Date and Time: The meeting will be held on December 6, 1999, 9 a.m. to 6:30 p.m., and December 7, 1999, 8:30 a.m. to 3 p.m.

Location: Gaithersburg Marriott Washingtonian Center, 9751 Washingtonian Blvd., Gaithersburg, MD.

Contact Person: Veronica J. Calvin, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–1243, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12514. Please call the Information Line for up-to-date information on this meeting.

Agenda: On December 6, 1999, the committee will discuss, make recommendations, and vote on a premarket approval application for a device indicated for frequent, automatic, and noninvasive monitoring of glucose levels in adults with diabetes. On December 7, 1999, the committee will discuss and make recommendations on general issues regarding over-the-counter devices for measurement of vaginal pH. The discussion will include appropriate claims, study designs to support claims, performance expectations, and labeling.

Procedure: On December 6, 1999, from 9 a.m. to 6:30 p.m., and on December 7, 1999, from 9 a.m. to 3 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by November 24, 1999. On December 6, 1999, oral presentations from the public will be scheduled between approximately 9:15 a.m. and 9:45 a.m. and between approximately 5:15 p.m. and 5:45 p.m. On December 7, 1999, oral presentations from the public will be scheduled between approximately 9:30 a.m. and 10 a.m. and between approximately 2 p.m. and 2:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before November 24, 1999, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Closed Committee Deliberations: On December 7, 1999, from 8:30 a.m. to 9 a.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential commercial information (5 U.S.C. 552b(c)(4)) relating to these products.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: November 2, 1999.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 99–29352 Filed 11–9–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Health Care Financing Administration

OIG/HCFA Special Advisory Bulletin on the Patient Anti-Dumping Statute

AGENCY: Office of Inspector General (OIG) and Health Care Financing Administration (HCFA), HHS.

ACTION: Notice.

SUMMARY: This **Federal Register** notice, developed jointly by the OIG and HCFA, sets forth the Special Advisory Bulletin addressing requirements of the patient anti-dumping statute and the obligations of hospitals to medically screen all

patients seeking emergency services and provide stabilizing medical treatment as necessary to all patients, including enrollees of managed care plans, whose conditions warrant it. In developing this Special Advisory Bulletin, our goal is to provide clear and meaningful advice with regard to the application of the anti-dumping provisions, and to ensure greater public awareness of hospitals' obligations in providing emergency medical services to those individuals insured by managed care plans.

FOR FURTHER INFORMATION CONTACT: Robin Schneider, Office of Counsel to the Inspector General, (202) 619–1306.

SUPPLEMENTARY INFORMATION:

Background

In an effort to identify and eliminate fraud, waste and abuse in the Department's health care programs, the OIG periodically develops and issues Special Fraud Alerts and, with the cooperation of HCFA, Advisory Bulletins to alert health care providers and program beneficiaries about potential problems. On December 7, 1998, the OIG and HCFA jointly published a **Federal Register** notice (63 FR 67486) seeking input and comments from interested parties on a proposed bulletin designed to address the principal requirements of the patient anti-dumping statute—known as the Emergency Medical Treatment and Labor Act (EMTALA)—(section 1867 of the Social Security Act (the Act)) and to discuss how the requirements of that statutory provision apply to individuals insured by managed care plans. Section 1867 of the Act imposes specific obligations on Medicare-participating hospitals that offer emergency services with respect to individuals coming to the hospital and seeking treatment of possible emergency medical conditions. Specifically, the draft Special Advisory Bulletin sought to address: (1) The obligations of hospitals to provide appropriate medical screening examinations to all patients seeking emergency services and stabilizing treatment when necessary; (2) Some of the special concerns in the provision of emergency services to enrollees of managed care plans; (3) The rules governing Medicare and Medicaid managed care plans with respect to prior authorization requirements and payment for emergency services; and (4) what types of practices would serve to promote hospital compliance with the patient anti-dumping statute when managed care enrollees seek emergency services.

The proposed Special Advisory Bulletin attempted to be consistent with policies set forth in the *HCFA State Operations Manual on Provider Certification* (Transmittal No. 2, May 1998) which provides guidelines and investigative procedures for reviewing the responsibilities of Medicare participating hospitals. Hospitals should also be aware that regulations at 42 CFR part 422 implementing section 1852(d) of the Act govern Medicare+Choice organizations' obligations to pay for emergency services without regard to prior authorization or the treating hospital's relationship with the plan.

Summary of Major Issues Raised

The major issues raised by the over 150 commenters concerned dual staffing, prior authorization, the use of financial responsibility forms and advanced beneficiary notifications, and the handling of patient inquiries regarding the obligation to pay for emergency services. Additional comments were also received concerning voluntary withdrawal and the reporting of alleged patient dumping violations.

1. Dual Staffing

The majority of comments expressed concern about the impact of dual staffing in hospital emergency departments (EDs), and many expressed the view that dual staffing would lead to disparate standards in the ED by fostering ''separate but unequal treatment.'' Possible disparate standards cited dealt with physician credentialing, drug formularies, equal access and use of ancillary services, consistency in specialty referrals, waiting times and quality assurance. A number of emergency physicians commenting on the proposed bulletin indicated that dual staffing would function to protect the financial interests of managed care organizations rather than provide the highest quality of care to individuals; many hospitals believed that dual staffing would add layers of bureaucracy to the system thereby disrupting and delaying patient care. Of course, there may be countervailing considerations relating to the benefits of flexibility and creativity in structuring health delivery systems, and there is a lack of data to support some assertions by those opposing dual staffing. For the Federal Government to prohibit in advance, on a national level, arrangements which might increase access to health care services would require some greater likelihood of risk or harm than we currently foresee. (In this context, we note that States are able to restrict or prohibit dual staffing arrangements within their borders.) It may or may not become evident that dual staffing impedes the goals of EMTALA, or that it advances publicly beneficial goals of managed care and other innovations in health care delivery, such as coordination of services and health promotion. If we were to declare that all dual staffing arrangements violate EMTALA, we might unnecessarily prevent the development of health care delivery practices which could improve access to health care.

Thus, we have concluded that while dual staffing raises serious issues, it would not necessarily constitute a *per se* violation of the anti-dumping statute. However, certain practices or occurrences that could arise in a dually staffed emergency department or service could violate EMTALA. Examples of these potential violations are described below.

2. Prior Authorization

While supportive of the ''no prior authorization'' best practice outlined in the proposed bulletin, many commenters argued for expanding the reach of this approach beyond the current authority of HCFA and the OIG as well as the patient anti-dumping statute, by making the policy applicable not only to hospitals but also to health plans. Several commenters expressed concern that hospitals are being forced to accept the contracts offered by managed care plans, although they realize that if they comply with the prior authorization requirements in the contract, the hospital could be in violation of the patient anti-dumping statute. Commenters further indicated that unless prior authorization requirements are abandoned or prohibited altogether, huge bills could result for patients whose care had not been authorized in advance. Commenters also stated that the ''prudent layperson'' standard does not sufficiently protect a hospital's interest in receiving payment for the emergency services provided.

We were unable to resolve many of the commenters' concerns because we do not have the authority under the patient anti-dumping statute to mandate reimbursement for emergency services or to regulate non-Medicare and non-Medicaid managed care plans. However, we have amended the prior authorization section of the bulletin slightly to make it absolutely clear that an emergency physician is free to phone a physician in a managed care plan at any time for a medical consultation when it is in the best interest of the patient. Further, we have clarified that once stabilizing treatment is under way, a managed care plan may be contacted for payment authorization.

3. Use of Advance Beneficiary Notices (ABNs) or Other Financial Responsibility Forms

With regard to the use of ABNs, commenters indicated that Medicare requires ABNs to be provided to beneficiaries if the hospital is to be permitted to bill the beneficiary later for a non-covered service, even for services provided in an emergency context. Thus, if a Medicare managed care patient arrived at the hospital and the ED physician was concerned that the plan may not cover the service, the physician *must* have the patient sign an ABN or else be precluded from billing the patient for the service if the plan does not pay. Several comments indicated that many hospitals are using ABNs for non-Medicare patients as well, even though these hospitals should be able to bill these patients for services in any case. A number of commenters opposed making it a ''best practice'' for hospitals not to ask patients to complete financial responsibility forms upon registration, indicating that it is common practice that standard consent forms are signed at the time of registration which include an agreement that the patient will pay for services not covered by insurance. Commenters expressed the view that as long as this practice does not cause delay in screening and stabilization, it would be very inefficient for a hospital to have to engage in ''split registration.''

It continues to be our view that a hospital would violate the patient anti-dumping statute if it delayed a medical screening examination or necessary stabilizing treatment in order to prepare an ABN and obtain a beneficiary signature. The best practice would be for a hospital *not to give* financial responsibility forms or notices to an individual, or otherwise attempt to obtain the individual's agreement to pay for services before the individual's stabilizing treatment is under way. This is because the circumstances surrounding the need for such services, and the individual's limited information about his or her medical condition, may not permit an individual to make a rational, informed consumer decision.

It normally is permissible to ask for general registration information prior to performing an appropriate medical screening examination. The hospital may not, however, condition such a screening and further treatment upon the individual's completion of a financial responsibility form or provision of a co-payment for any services. Such a practice could unduly deter the individual from remaining at the hospital to receive care to which he or she is entitled and which the hospital is obligated to provide regardless of ability to pay, and could cause unnecessary delay.

With respect to the use of financial responsibility forms, we believe that many commenters mistakenly interpreted the proposed bulletin as an attempt to derail the use of reasonable hospital registration procedures that do not conflict with the goals of the Patient Anti-Dumping Statute. We did not mean to give that impression. We are therefore clarifying this portion of the Special Advisory Bulletin consistent with the specific language set forth in the *HCFA State Operations Manual,* Interpretive Guidelines of May 1998, regarding registration processes permitted in the ED, which typically include the collection of demographic information, insurance information, whom to contact in an emergency and other relevant information. Specifically, the Interpretive Guidelines indicate that a hospital ''may continue to follow reasonable registration processes for individuals presenting with an emergency medical condition.'' Reasonable registration processes should not unduly discourage individuals from remaining for further evaluation. Reasonable registration processes may include asking whether an individual is insured and, if so, what that insurance is, as long as this inquiry does not delay screening or treatment.

We are also clarifying that, while a reasonable registration process may go forward prior to screening for an individual who is not in an acute emergency situation, it would be impermissible for a hospital to condition a screening examination or the commencement of necessary stabilizing treatment on completion of a financial responsibility form.

4. Inquiries Concerning Financial Liability for Emergency Services by the Individual

With regard to a hospital's handling of patient inquiries regarding the patient's obligation to pay for emergency services, we recommended in the proposed bulletin that such questions be answered by qualified personnel. We also recommended that hospital staff encourage a patient who believes that he or she may have an emergency medical condition to defer any further discussions of financial responsibility until after the provision of an appropriate medical screening examination and the provision of stabilizing treatment if the patient's condition warrants it. Many commenters disagreed with this recommendation, indicating that such a deferral may have the opposite of the intended result, since patients who are unable to determine their potential financial liability may be discouraged from staying at the hospital to receive an examination or treatment. As an alternative, commenters recommended that hospital staff be permitted to respond to patient inquiries with specific financial information so long as the hospital continues to offer, and encourages the patient to stay for, a medical screening examination. In addition, commenters were concerned that the absence of full and frank disclosure between physicians and patients regarding treatment options, insurance coverage and follow-up treatment would inhibit the examination and treatment process. These commenters recommended allowing conversations about financial liability issues to take place between hospital staff and patients so long as such discussions do not delay screening and treatment.

We have not substantially revised this section. We believe that it already makes clear that any inquiry about financial liability should be answered as fully as possible by a qualified individual. Alternatives suggested by the commenters would be acceptable if such alternatives did not conflict with a minimum effort to defer discussions about financial liability issues until after the provision of screening and the commencement of stabilizing treatment. This section does not suggest that a patient is not entitled to full disclosure, only that the hospital should always convey to the patient that screening and stabilization are its priorities regardless of the individual's insurance coverage or ability to pay and that the hospital should discuss, to the extent possible, the medical risks of leaving without a medical screening exam and/or stabilizing treatment.

5. Voluntary Withdrawal

Commenters also raised concerns about the hospital's obligation in the event of voluntary withdrawal by an individual, and the proposed bulletin's suggestion that a number of procedures be followed and documented when a patient elects to withdraw his or her request for treatment. Commenters believed that the proposed procedures do not make allowance for those times when a hospital is not aware of the individual's departure until after he or she has left the hospital. Commenters recommended that the steps set forth in the draft bulletin should apply only when the hospital knows of the withdrawal, that is, when possible, and that when a person leaves without

telling hospital staff, a hospital be required to document the fact that a patient simply left without notice and retain the log that shows that the person had been there and what time the hospital discovered that the patient had left. We have revised this section to some extent. However, it is our view that hospitals should be very concerned about patients leaving without being screened. Since every patient who presents seeking emergency services is entitled to a screening examination, a hospital could violate the patient anti-dumping statute if it routinely keeps patients waiting so long that they leave without being seen, particularly if the hospital does not attempt to determine and document why individual patients are leaving, and reiterate to them that the hospital is prepared to provide a medical screening if they stay.

In accordance with our assessment of the comments and issues raised, set forth below is the revised OIG/HCFA Special Advisory Bulletin addressing the patient dumping statute.

Obligations of Hospitals To Render Emergency Care to Enrollees of Managed Care Plans

What are the Obligations of Medicare-Participating Hospitals That Offer Emergency Services to Individuals Seeking Such Services?

- The anti-dumping statute (section 1867 of the Social Security Act; 42 U.S.C. 1395dd) sets forth the federally-mandated responsibilities of Medicare-participating hospitals to individuals with potential emergency medical conditions.
- Under the anti-dumping statute, a hospital must provide to any person who comes seeking emergency services an appropriate medical screening examination sufficient to determine whether he or she has an emergency medical condition, as defined by statute. When medically appropriate, ancillary services routinely available at the hospital must be provided as part of the medical screening examination.
- If the person is determined to have an emergency medical condition,

—The hospital is required to stabilize the medical condition of the individual, within the capabilities of the staff and facilities available at the hospital, prior to discharge or transfer; or

—If the patient's medical condition cannot be stabilized before a transfer requested by the patient (or responsible medical personnel determine that the medical benefits of a transfer outweigh the risks), the hospital is required to follow very specific statutory requirements designed to facilitate a safe transfer to another facility.

- A hospital may not delay the provision of an appropriate medical screening examination or further medical examination and stabilizing medical treatment in order to inquire about the individual's method of payment or insurance status.
- Regulations implementing these statutory obligations are found at 42 CFR part 489. The anti-dumping statute is enforced jointly by the Health Care Financing Administration (HCFA) and the Office of Inspector General (OIG) of the U.S. Department of Health and Human Services (HHS).
- Sanctions that may be imposed by HHS for violations of the anti-dumping statute include the termination of the hospital's provider agreement, and the imposition of civil money penalties against both the hospital and the physician (including on-call physicians) responsible for examination, treatment, or transfer of an individual. In addition, the anti-dumping statute provides for the exclusion of such physician if the violation is gross and flagrant or repeated.

Why is there a Special Concern About the Provision of Emergency Services to Enrollees of Managed Care Plans?

Many managed care plans require their members to seek prior authorization for some medical services, including emergency services. (As explained below, a Medicare or Medicaid contracting Managed Care Organization is prohibited from requiring its members to seek prior authorization for emergency medical services.) However, as noted above, the anti-dumping statute prohibits a hospital's inquiry about a patient's method of payment or insurance status, or use of such information, from delaying a screening examination or stabilizing medical treatment. It has come to our attention that some hospitals routinely seek prior authorization from a patient's primary care physician or from the plan when a managed care patient requests emergency services, since the failure to obtain authorization may result in the plan refusing to pay for the emergency services. In such circumstances, the patient may be personally liable for the costs.

A reasonable argument can be made that patients (other than those arriving in dire condition) should be informed when they request emergency services of their potential financial liability for services. Some would go further and argue that the hospital itself should seek prior approval from the patient's health plan for emergency services to preserve the patient's right to seek coverage for such services. However, our concern is that such an inquiry may improperly or unduly influence patients to leave the hospital without receiving an appropriate medical screening examination. This result would be inconsistent with the goals of the anti-dumping statute and could leave the hospital exposed to liability under the statute.

Investigations of allegations of the anti-dumping statute violations across the country have persuaded the OIG and HCFA that managed care patients may be at risk of being discharged or transferred without receiving a medical screening examination, largely because of the problems inherent in seeking ''prior authorization.'' Hospitals sometimes are caught between the legal obligations imposed under the anti-dumping statute and the terms of agreements which they have with managed care plans. For example, some managed care organizations, as a condition of contracting with hospitals to provide services to their enrollees, have attempted to require such hospitals to obtain prior authorization from the plan before screening or treating an enrollee in order to be eligible for reimbursement for services provided.

The OIG's and HCFA's view of the legal requirements of the anti-dumping statute in this situation is as follows. Notwithstanding the terms of any managed care agreements between plans and hospitals, the anti-dumping statute continues to govern the obligations of hospitals to screen and provide stabilizing medical treatment to individuals who come to the hospital seeking emergency services regardless of the individual's ability to pay. While managed care plans have a financial interest in controlling the kinds of services for which they will pay, and while they may have a legitimate interest in deterring their enrollees from over-utilizing emergency services, no contract between a hospital and a managed care plan can excuse the hospital from its anti-dumping statute obligations. Once a managed care enrollee comes to a hospital that offers emergency services, the hospital must provide the services required under the anti-dumping statute without regard for the patient's insurance status or any prior authorization requirement of such insurance.[1]

[1] Separate and apart from the anti-dumping statute, in accordance with sections 1857(g), 1876(i)(6), 1903(m)(5) and 1932(e) of the Social Security Act, the OIG (acting on behalf of the Secretary) has the authority to impose intermediate sanctions against Medicare and Medicaid contracting managed care plans that fail to provide medically necessary services, including emergency

What About Arrangements Between Hospitals and Managed Care Plans for ''Dual Staffing'' of Emergency Departments?

Some managed care organizations (MCOs) and hospitals have entered into, or are considering entering into, arrangements whereby the hospital permits the MCO to station its own physicians in the hospital's emergency department, separate from the hospital's own emergency physician staff, for the purpose of screening and treating MCO patients who request emergency services. This kind of arrangement is known as ''dual staffing.''

Such arrangements can exist only where they do not violate current law. Regardless of any contractual arrangement a hospital enters into to staff its emergency department, the hospital remains responsible under EMTALA to provide an appropriate medical screening examination to determine whether or not an emergency medical condition (EMC) exists. If an EMC exists, EMTALA further provides that the hospital must treat and stabilize the medical condition, unless the patient is transferred in accordance with the specific requirements of the statute.

Also, section 1867(h) of the Act provides that a participating hospital, in providing emergency medical care, ''may not delay provision of an appropriate medical screening examination * * * or further medical examination and treatment * * * in order to inquire about the individual's method of payment or insurance status.'' A dual staffing system, based on method of payment or insurance status, which creates delays in screening or stabilization violates this prohibition. Also, the hospital remains responsible under the Medicare Conditions of Participation as well as any other relevant patient protections and quality safeguards. Further, the hospital is bound by provisions that protect whistle blowers who report violations of EMTALA in dual staffing situations.

Different points of view on dual staffing exist in the health care community. It is believed by some that dual staffing in emergency departments can facilitate the expeditious provision of services to MCO patients by physicians and other practitioners in their own health plans. MCO ability to care for their patients after stabilization, or after the absence of an EMC is determined, might be enhanced by dual staffing. However, some hospitals and emergency physicians have asked us to disallow dual staffing out of concern for logistical difficulties and the perception that separate cannot be equal in a bifurcated emergency department.

If a hospital constructs two equally good emergency service ''tracks,'' each adequately staffed and each with equally good access to all of the medical capabilities of the hospital, such that both MCO and non-MCO patients receive equal access to screening and stabilizing medical treatment, then such an arrangement would seem to not violate the requirements of the anti-dumping statute.

Absent such equivalency, implementation of dual staffing raises concerns under EMTALA. The following are potential violations:

- Where the emergency department directs a hospital-owned and operated ambulance differently in field care or facility destination depending on which members of a dual staff (that is, either MCO or non-MCO physicians or practitioners) are either on the radio to emergency medical services (EMS) or are expected to see the patient.
- If the emergency department alert status affecting acceptance of EMS cases differs depending on which ''side'' (MCO or non-MCO) is expected to see the patient.
- If either the MCO or non-MCO track is understaffed or simply overcrowded, and a patient in a particular track is subjected to a delay in screening and stabilizing treatment, even though a physician in the alternative track was available to see the individual. Where there is no emergency department policy or procedure, or custom or practice, which requires cross-over coverage between the dual staffs as required for patient care. (Delays in screening or stabilization of patients on one track but not the other are delays in screening or stabilization based on the insurance status of the individual and thus represent potential violations of EMTALA.)
- If the hospital's emergency department quality oversight plan differs between the two ''sides'' (MCO and non-MCO) of the dually staffed ED.
- Where the protocols for transfer of unstable patients differ other than administratively, for example, (1) if the substance of stability determination criteria between the two staffs are different, or (2) when patients are unstable and are transferred routinely to different facilities that are not equivalent to each other in level of care or distance, and their destinations depend on their insurance status.

While we recognize that dual staffing will add to a hospital's burden to assure that it is not violating EMTALA, we do not believe the EMTALA statute makes dual staffing illegal *per se.* We expect that practical experience with dually staffed emergency departments will reveal whether or not they can be maintained without violating EMTALA.

What Are the Rules Governing Medicare and Medicaid Managed Care Plans With Respect to Prior Authorization Requirements and Payment for Emergency Services?

There are special requirements for managed care plans that contract with Medicare and Medicaid to provide services to beneficiaries of those programs. Congress has specified that Medicare and Medicaid managed care plans may not require prior authorization for emergency services, and must pay for such services, without regard to whether the hospital providing such services has a contractual relationship with the plan. Under statutory amendments recently enacted in the Balanced Budget Act (BBA) of 1997 (Public Law 105–33)[2], Medicare and Medicaid managed care plans are prohibited from requiring prior authorization for emergency services, including those that ''are needed to evaluate or stabilize an emergency medical condition.'' Moreover, Medicare and Medicaid managed care plans are required to pay for emergency services provided to their enrollees. The obligation to pay for emergency services under Medicare managed care contracts is based on a ''prudent layperson'' standard, which means that the need for emergency services should be determined from a reasonable patient's perspective at the time of presentation of the symptoms.[3]

services, to enrollees where the failure adversely affects (or has a substantial likelihood of adversely affecting) the enrollee. Medicare and Medicaid managed care plans that fail to comply with the above provision are subject to civil money penalties of up to $25,000 for each denial of medically necessary services.

[2] See section 4001 of the BBA, which created section 1852(d) of the Act. Section 1852(d) covers emergency services and prior authorization for Medicare enrollees. Also, section 4704(a) of the BBA created section 1932(b) of the Act, which contains Medicaid provisions covering emergency services and prior authorization.

[3] With respect to Medicare, prior authorization requirements for Medicare MCO plans were already explicitly prohibited by regulations before the passage of the BBA for emergency services provided outside an HMO or competitive medical plan (42 CFR 417.414(c)(1)), and by implication for services provided within such a plan. Similarly, while the BBA clarified and codified the ''prudent layperson'' standard, a variation of this standard has always been part of the Medicare policy for managed care plans. Even prior to the BBA, Medicare and Medicaid managed care plans were required to reimburse for emergency services provided other than through the organization. See section 1876(c)(4)(B), 42 CFR 417.414(c)(1) for Medicare and section 1903(m)(2)(A)(vii), 42 CFR 434.30(b)(2) for Medicaid.

What Practices Will Promote Compliance With the Anti-Dumping Statute by Hospitals When Managed Care Enrollees Seek Emergency Services?

The OIG and HCFA are concerned that discussion by hospital personnel with a patient regarding the possible need for prior authorization, or his or her potential financial liability for medical services provided by a hospital that offers emergency services, could unduly influence patients to leave the emergency department without receiving an appropriate medical screening examination or any necessary stabilizing treatment. Without also informing the patient of his or her rights to a medical screening examination and to stabilizing medical treatment if the patient's condition warrants it and the medical risks of leaving, a discussion about insurance, ability to pay and seeking prior authorization may impede a hospital's compliance with its obligations under the anti-dumping statute. Discussions initiated by a hospital staff member with a patient regarding potential prior authorization requirements and their financial consequences that have the effect of delaying a medical screening are per se violations of the anti-dumping statute. Moreover, the OIG and HCFA believe that in the absence of an initial screening, the decision of a managed care plan regarding the need for treatment is likely to be ill-informed. Patients are entitled to receive a medical screening examination and stabilizing medical treatment under the anti-dumping statute regardless of a hospital's contract with a health plan that requires prior authorization. Accordingly, the OIG and HCFA suggest the following practices to minimize the likelihood that a hospital will violate the statute:

- *No Prior Authorization Before Screening or Commencing Stabilizing Treatment*

It is not appropriate for a hospital to seek, or direct a patient to seek, authorization to provide screening or stabilizing services to an individual from the individual's health plan or insurance company until after the hospital has provided (1) an appropriate medical screening examination to determine the presence or absence of an emergency medical condition, and (2) any further medical examination and treatment necessary to commence stabilization of an emergency medical condition. The hospital may seek authorization for payment for all services after providing a medical screening examination and once necessary stabilizing treatment is underway. (We recognize that this guidance differs in part from that provided in the *HCFA State Operations Manual on Provider Certification* (Transmittal No. 2, May 1988, Interpretive Guidelines—Responsibilities of Medicare Participating Hospitals in Emergency Cases, Data Tag No. A406, p. V–20), which states that ''it is not appropriate for a hospital to request or a health plan to require prior authorization before a patient has received a medical screening exam to determine the presence or absence of an emergency medical condition or until an emergency medical condition has been stabilized.'' We will revise the *State Operations Manual* to ensure that it conforms to the guidance provided in this bulletin) We wish to emphasize that an emergency physician is not precluded from contacting the patient's personal physician at any time to seek advice regarding the patient's medical history and needs that may be relevant to the medical screening and treatment of the patient, as long as this consultation does not inappropriately delay such screening and stabilization.[4]

- *Use of Advance Beneficiary Notices and other Financial Responsibility Forms*

A hospital would violate the patient anti-dumping statute if it delayed a medical screening examination or necessary stabilizing treatment in order to prepare an ABN and obtain a beneficiary signature. The best practice would be for a hospital *not to give* financial responsibility forms or notices to an individual, or otherwise attempt to obtain the individual's agreement to pay for services before the individual is stabilized. This is because the circumstances surrounding the need for such services, and the individual's limited information about his or her medical condition, may not permit an individual to make a rational, informed consumer decision. It normally is permissible to ask for general registration information prior to performing an appropriate medical screening examination. The hospital may not, however, condition such a screening and further treatment upon the individual's completion of a financial responsibility form or provision of a co-payment for any services. Such a practice could unduly deter the individual from remaining at the hospital to receive care to which he or she is entitled and which the hospital is obligated to provide regardless of ability to pay, and could cause unnecessary delay. In accordance with the *HCFA State Operations Manual,* Interpretative Guidelines, V–27 (May 1998), a hospital may continue to follow reasonable registration processes for individuals presenting for evaluation and treatment of a medical condition. Reasonable registration processes may include asking whether an individual is insured and, if so, what that insurance is, as long as this inquiry does not delay screening or treatment. However, reasonable registration processes should not unduly discourage patients from remaining for further evaluation.

- *Qualified Medical Personnel Must Perform Medical Screening Examinations and Physicians Must Authorize Transfers*

A hospital should ensure that either a physician or other qualified medical personnel (that is, hospital staff approved by the hospital's governing body to perform certain medical functions) provides an appropriate medical screening examination to *all* individuals seeking emergency services. Depending upon the individual's presenting symptoms, this screening examination may range from a relatively simple examination to a complex one which requires substantial use of ancillary services available at the hospital and on-call physicians. If it is determined that the individual has an emergency medical condition and that the individual requires a transfer, only a physician (or, if a physician is not physically present in the emergency department at the time, a qualified medical person in consultation with a physician in accordance with regulations at 42 CFR 489.24(d)(1)(ii)(C)) may authorize such a transfer.

- *When a Patient Inquires About Financial Liability for Emergency Services*

If a patient inquires about his or her obligation to pay for emergency services, such an inquiry should be answered by a staff member who has been well trained to provide information regarding potential financial liability. This staff member also should be knowledgeable about the

[4] If, when contacted, a managed care physician requests that the patient be transferred, the hospital must still conclude the medical screening examination and provide any treatment necessary to stabilize the patient prior to transfer, or in the case of an unstable patient, provide an appropriate transfer. A hospital may only transfer an unstable patient at the request of the managed care physician when either a physician at the hospital certifies that the medical benefits of transfer outweigh the increased risk, or when the patient requests the transfer in writing after being informed of the hospital's obligations and the risks of transfer.

hospital's anti-dumping statute obligations and should clearly inform the patient that, notwithstanding the patient's ability to pay, the hospital stands ready and willing to provide a medical screening examination and stabilizing treatment, if necessary. Hospital staff should encourage any patient who believes that he or she may have an emergency medical condition to remain for the medical screening examination and any necessary stabilizing treatment. Staff should also encourage the patient to defer further discussion of financial responsibility issues, if possible, until *after* the medical screening has been performed. If the patient chooses to withdraw his or her request for examination or treatment, a staff member with appropriate medical training should discuss the medical issues related to a ''voluntary withdrawal.''

- *Voluntary Withdrawal*

If an individual chooses to withdraw his or her request for examination or treatment at the presenting hospital, and if the hospital is aware that the individual intends to leave prior to the screening examination, a hospital should take the following steps: (1) Offer the individual further medical examination and treatment within the staff and facilities available at the hospital as may be required to identify and stabilize an emergency medical condition; (2) Inform the individual of the benefits of such examination and treatment, and of the risks of withdrawal prior to receiving such examination and treatment; and (3) Take all reasonable steps to secure the individual's written informed consent to refuse such examination and treatment. The medical record should contain a description of risks discussed and of the examination, treatment, or both, if applicable, that was refused. If an individual leaves without notifying hospital personnel, the hospital should, at a minimum, document the fact that the person had been there, what time the hospital discovered that the patient had left, and should retain all triage notes and additional records, if any. However, the burden rests with the hospital to show that it has taken appropriate steps to discourage an individual from leaving the hospital without evaluation.

Dated: November 4, 1999.

June Gibbs Brown,

Inspector General, Office of Inspector General.

Dated: November 3, 1999.

Michael M. Hash,

Deputy Administrator, Health Care Financing Administration.

[FR Doc. 99–29390 Filed 11–9–99; 8:45 am]

BILLING CODE 4150–04–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Licensing Opportunity and/or Cooperative Research and Development Agreement (''CRADA'') Opportunity; Certain Live Attenuated Respiratory Syncytial Viruses (RSV) and Parainfluenza Viruses (PIV) for Use as Human Vaccines

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

ACTION: Notice.

SUMMARY: The National Institutes of Health (NIH) is seeking Licensee(s) and/or a commercial collaborator(s) to further develop, test, and commercialize as live attenuated vaccines certain recombinant RSV and PIV strains and associated intellectual property developed in the Laboratory of Infectious Diseases (LID), Division of Intramural Research, National Institute of Allergy and Infectious Diseases (NIAID).

DATES: There is no date by which license applications must be received. Respondents who wish to be considered for the CRADA opportunity must submit a Capability Statement (described below in **SUPPLEMENTARY INFORMATION**) to the NIAID. Only written Capability Statements received by the NIAID on or before December 27, 1999 for consideration. Capability Statements should be forwarded to Michael R. Mowatt, Ph.D. at the address specified below.

FOR FURTHER INFORMATION CONTACT: Inquiries about these licensing opportunities should be addressed to Robert Benson, Ph.D., Patent Advisor, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804, Telephone: (301) 496–7056 ext. 267; Facsimile: (301) 402–0220; Email: rb20m@nih.gov. Information about Patent Applications and pertinent information not yet publicly described can be obtained under the terms of a Confidential Disclosure Agreement. Respondents interested in licensing the inventions will be required to submit an ''Application for License to Public Health Service Inventions''.

Inquiries about the CRADA opportunity should be addressed to Michael R. Mowatt, Ph.D., Technology Development Manager, Office of Technology Development, NIAID, Building 31 Room 3B62, 31 Center Drive MSC 2137, Bethesda, MD 20892–2137, Telephone: (301) 435–8618, Facsimile: (301) 402–7123; Email: mmowatt@nih.gov. Respondents interested in the CRADA opportunity should be aware that it might be necessary to secure a license to the above-mentioned patent rights in order to commercialize products arising from a CRADA.

SUPPLEMENTARY INFORMATION: The inventions described below are owned by an agency of the U.S. Government and are available for licensing—in accordance with 35 U.S.C. 207 and 37 CFR part 404 to achieve expeditious commercialization of results of federally-funded research and development—and/or further development under one or more CRADAs in the clinically important applications described below.

Human Respiratory Syncytial Viruses (HRSV), subgroups A and B (HRSV–A and HRSV–B, respectively), are the most common cause of serious respiratory tract infection in children and infants less than one year of age. RSV is responsible for more than 20% of all pediatric hospital admissions due to respiratory tract disease, and in the US is the cause of 91,000 hospitalizations and 4,500 deaths. No licensed vaccine is available to prevent disease by these viruses.

Attenuated RSV strains for intranasal administration are the most promising candidate vaccines because they are efficacious even in the presence of passively transferred antibodies, the very situation found in the target population of infants with maternally derived anti-HRSV antibodies. Designed mutations can be introduced into the RSV genome or antigenome utilizing cDNA technology as a means of engineering suitably attenuated RSV strains. See Collins *et al.*, Proc. Nat. Acad. Sci. USA *92* 11563–11567, 1995, and PCT/US96/15524, ''Production of Infectious Respiratory Syncytial Virus From Cloned Nucleotide Sequences'', which is available from NIH for licensing nonexclusively.

Human Parainfluenza Viruses (HPIV), serotypes 1, 2, and 3 (HPIVs, HPIV2, and HPIV1, respectively), are in aggregate the second most common