views and access the HCFA Online Application System at http://www.hcfa.gov/oaas. To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA’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 HCFA document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786-1326.

Interested persons are invited to send comments regarding the burden or any other aspect of these collections of information requirements. However, as noted above, comments on these information collection and recordkeeping requirements must be mailed and/or faxed to the designees referenced below, by 03/23/98:


John P. Burke III, HCFA Reports Clearance Officer, HCFA, Office of Information Services, Information Technology Investment Management Group, Division of HCFA Enterprise Standards.

BILLING CODE 4120±03±P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA±1103±GN]

Medicare Program; HCFA Market Research for Providers and Other Partners

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: General notice with comment period.

SUMMARY: This notice seeks public comments on information needs of Medicare risk contract health maintenance organizations (HMOs) and competitive medical plans (CMPs) and communication strategies that could improve the effectiveness and efficiency of the risk contract program. Under section 4002 of the Balanced Budget Act of 1997, and with the implementation of the Medicare+Choice program, all HMOs and CMPs will contract with HCFA under requirements of the Medicare+Choice program. The information sought in this notice will facilitate future changes in the contracting program, as well as improve information needs and communication strategies under the current risk program. Respondents should prioritize issues raised in the preliminary research and identify any additional areas of information needs and best communication strategies.

This initiative is one component of our overall effort to develop a comprehensive communication strategy with Medicare providers and HMOs/CMPS and to develop innovative approaches that will assist all program participants to obtain and use information in the most accessible and effective manner. Preliminary research on the information needs of Medicare risk contract HMOs and CMPS and effective communication strategies has identified a number of areas in which we could provide additional information and potential strategies for communicating that information effectively.

DATES: Written comments will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on May 4, 1998.

ADDRESSES: Mail written comments (one original and three copies) to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: HCFA±1103±GN, P.O. Box 26676, Baltimore, MD 21207.

If you prefer, you may deliver your written comments (one original and three copies) to one of the following addresses:

Room 309±G, Hubert H. Humphrey Building, 200 Independence Avenue, SW, Washington, DC 20201, or Room C5±09±26, 7500 Security Boulevard, Baltimore, MD 21244±1850.

Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code HCFA±1103±GN. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 309±G of the Department’s offices at 200 Independence Avenue, SW, Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone: (202) 690±7890).

Comments may also be submitted electronically to the following e-mail address: HCFA±1103±GN@hcfa.gov. E-mail comments must include the full name and address of the sender and must be submitted to the referenced address in order to be considered. All comments must be incorporated in the e-mail message because we may not be able to access attachments. Electronically submitted comments will also be available for public inspection at the Independence Avenue address above.

FOR FURTHER INFORMATION CONTACT: Sherry Terrell (410) 786±6601.

SUPPLEMENTARY INFORMATION:

I. Background

Section 1876 of the Social Security Act (the Act) authorizes Medicare payment to health maintenance organizations (HMOs) and competitive medical plans (CMPS) that contract with HCFA to furnish covered services to Medicare beneficiaries. For purposes of
this notice the term HMO includes both CMPs and HMOs. To apply for and be approved to operate as a Medicare risk contractor, HMOs must be licensed in the State in which they operate and have at least 5,000 commercial members. Most HMOs that have applied for Medicare contracts have at least several years of experience managing commercial enrollments and existing operational systems in place. Even for HMOs with many years of experience, however, applying for a Medicare risk contract may require substantial investments of staff time and significant costs. Our requirements for participation, the extent of our oversight of risk contracts, and ongoing interaction between the HMO and HCFA are generally much greater than HMOs' experience in obtaining and maintaining State licensure and in serving commercial clients.

Because of these different requirements, information and communication processes between the HMO and HCFA are an important component of the Medicare risk contracting program. HMOs that are applying for Medicare risk contracts need information and guidance in understanding our requirements in order to ensure that their operational systems and approach to Medicare contracting meets those requirements. Once approved and operational, risk contract HMOs have ongoing needs for information and communication with us in order to operate successfully and to remain in compliance with our standards.

Our information comes from a number of different sources, including Peer Review Organizations (PROs) and other contractors, who are responsible for specific operational functions.

HMOs are responsible for obtaining, understanding, and integrating into their operations the information available from all these sources and for seeking clarification of specific aspects of the risk contract process, when necessary. Table 1 summarizes the major areas of responsibility for providing information and ongoing communication with risk contract HMOs for each of these information sources.

### Table 1.—HCFA Information Sources

<table>
<thead>
<tr>
<th>Source</th>
<th>Information responsibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>HCFA Central Office</td>
<td>Legal, regulatory, and financial issues.</td>
</tr>
<tr>
<td></td>
<td>Payment Process.</td>
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<tr>
<td></td>
<td>Accretion/Deletion Process.</td>
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<tr>
<td></td>
<td>Application.</td>
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<tr>
<td></td>
<td>Site Visit.</td>
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<td></td>
<td>Operational requirements/review.</td>
</tr>
<tr>
<td>HCFA Regional Office</td>
<td>Review marketing materials and other beneficiary communications.</td>
</tr>
<tr>
<td>Peer Review Organizations</td>
<td>Monitoring site visits and follow-up retroactive enrollments.</td>
</tr>
<tr>
<td>Other Contractors Intermediaries and Carriers</td>
<td>Communications on cooperative quality improvement projects.</td>
</tr>
<tr>
<td>CHDR</td>
<td>Investigation and follow-up of beneficiary complaints and non-coverage notices.</td>
</tr>
<tr>
<td>NCQA</td>
<td>Coverage decisions (for example, local carriers medical review policies).</td>
</tr>
<tr>
<td>ACR Review</td>
<td>Payment rates for out-of-area services.</td>
</tr>
<tr>
<td></td>
<td>Health dispute resolution.</td>
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</tbody>
</table>

II. The Application Process

Undertaking a Medicare risk contract requires that HMOs address a number of issues that are different from their commercial enrollment and service delivery processes. The differences between the experience of HMOs in operating a commercial HMO based on employer contracts and the requirements for a Medicare risk contract makes it likely that an HMO beginning the Medicare risk application process will obtain assistance from some source that has prior experience in Medicare risk contracting. For HMOs that are part of a national chain that has other Medicare risk contracts, that experience may come from a group in the corporate office of the chain. Other HMOs may hire an individual with prior Medicare risk contract experience to lead the application and implementation processes. Many HMOs hire consulting firms with Medicare risk contract experience to guide them through the process of applying and to assist in preparation of the application.

If requested, we will provide information to clarify requirements. Establishing the correct lines of communication early in the process is essential to the HMO’s ability to develop a successful Medicare application.

A. Ongoing Operations

Once we have approved the application submitted by the HMO, implementation and ongoing operations of the Medicare risk plan requires continuing interaction and information exchange between the HMO and HCFA. We have specific responsibilities with respect to communication with the HMO. We delegate some of our responsibilities for quality assurance to PROs that work directly with the HMOs. We also use contractors to handle some functions; for example, we contract for Adjusted Community Rating (ACR) review services and this contractor deals directly with each HMO to obtain information and clarify submissions before completing a preliminary review and forwarding the ACR submissions to us for approval. In addition, HMOs require information from intermediaries and carriers to coordinate coverage decisions and to pay out-of-area providers. HMOs also must work with the Center for Health Dispute Resolution (CHDR) on reconsideration.

The operational Medicare risk HMO maintains close communication with us on an ongoing or periodic basis for the following functions and requirements:

- Marketing Materials and Plans. The HMO must obtain advance approval of any materials that will be used to market to, or communicate with, Medicare beneficiaries.
- Enrollment and Disenrollment. The HMO submits monthly lists of new enrollees and disenrolled members to our data system either directly or through a contractor (for example, CompuServe) that we use to determine payment. Discrepancies require resolution that involve interaction between the HMO and HCFA.
- Quality Assurance. The HMO must provide information to HCFA Central and Regional Offices and may
HMOs must provide HEDIS® data to us, through our contractor, the National Committee for Quality Assurance (NCQA); and participate in the Consumers Assessments of Health Plans Study (CAHPS) survey of Medicare beneficiaries. Working with the HMO staff, the PRO also follows up with HMO member complaints, grievances, and appeals. We can also request corrective action plans for quality related issues and monitor compliance.

- Financial. Annually, the HMO must prepare financial projections and analyses to support the benefit package and premiums that will be offered to Medicare beneficiaries. We currently use a contractor to initiate the ACR review process and to work with the HMOs to clarify components of the HMO’s submission. Our final review and approval process may involve further requests for information and clarification.
  - New Regulations and Changes in Regulations. We develop new regulations based on legislation and make revisions in existing regulations. In some cases, the HMOs are asked to provide information necessary for the development of new regulations and to provide data, information, or comments on these regulations while in the developmental stage. The final regulation is then published in the Federal Register. If necessary, we may provide clarification and elaboration of the intent and operational implications of the new regulation.
  - Ongoing Monitoring and Reporting. Medicare HMOs are responsible for regular reporting to us. Site visits to each HMO are conducted bi-annually by our staff. The site visits are comprehensive in nature and normally include review of every operational area of the HMO. Following the site visit, we notify the HMO of any areas in which deficiencies were identified and ask it to prepare a corrective action plan. We will provide direction to other entities with which the HMOs communicate.

### B. Preliminary Research

In discussions with several Medicare risk contract HMOs, PROs, and others, we have identified a preliminary list of information needs that are not currently being fully met. These information items are summarized in Table 2 for HMOs in the application process and in Table 3 for operational Medicare risk contract HMOs.

#### Table 2.—Additional Information That Would Be Useful During the Application Period

| A. Basic information on Medicare and operational information on risk contracting, including: | • HCFA manuals;  
| | • Operational Policy Letters (OPLs);  
| | • Transmittal Letters;  
| | • Guidelines and regulations, such as National Marketing Guidelines, and Physician Incentive Plan regulations;  
| | • Organizational structure of HCFA;  
| | • Informing applicants of the duration of the application review process and providing a contact person for the review;  
| | • Informing applicants when there is a delay in the process, and of the reason for the delay;  
| | • Published documents, with a brief description of contents, and instructions on how to obtain them and;  
| | • Names of contacts, by operational area, with e-mail addresses and telephone numbers.  
| B. Sources of information, including: | • Medicare utilization statistics, by geographic area;  
| C. Information and data, including: | • Information on studies conducted by, or supported by, HCFA on managed care quality, outcomes, utilization patterns, special population needs, and “best practices”;  
| | • Results of quality of care studies and outcomes surveys, by area of country and type of facility;  
| | • Quality measurement by hospital and skilled nursing facility (SNF), to assist in recruiting quality facilities for the provider networks;  
| | • Regulations affecting HMOs, hospitals, physicians, and other providers;  
| | • Listings of Diagnosis-Related Group (DRG)-exempt facilities; and,  
| | • Physician fee schedules and DRG payment rates for hospitals.  

#### Table 3.—Information Wanted/Needed by Medicare Risk Contractor HMOs

| A. Upon Contract Award:  
| Operational Information ....................... | • Provide a basic package of materials (interviewees suggested that this occur during the application process).  
| | • Provide written advice on key set-up issues, such as expected interactions with PROs, CHDR, local carriers and intermediaries; availability of use of MCCOY, CompuServe, and/or Litton; systems and reporting requirements and the format in which they must be provided.  
| B. Operational Information:  
| 1. Carrier and Intermediary .................. | • Provide clearer examples of what services and procedures are covered, as determined by local carriers and fiscal intermediaries, especially for controversial medical areas.  
| | • Provide appropriate local prevailing physician Medicare fee schedules to determine reimbursement of out-of-area care.  
| 2. Accretion and Deletion Process .......... | • Provide a complete and accurate listing of codes used in reports, such as Reply Listings and Exception Detail; include accurate and current institutional status code on Special Reply.  
| | • Label cumulative 6-month report with start and end dates and disseminate the anticipated release schedule.  
| | • Enable Litton/CompuServe to provide corrected information with the list of errors. Presently, HMOs have to look up the information although Litton/CompuServe have the information available.  
| | • Develop industry standards and methodology for calculation of voluntary disenrollment rates.  
| | • Summarize changes made in manuals given to plans on an annual basis.  
| | • Inform HMOs on a regular basis on the status of marketing materials in the review process.  
| 3. Marketing .................................. |
A number of information process issues have also been identified in these limited preliminary discussions. Process issues relate to timeliness and completeness of information that we provide to Medicare risk contract HMOs and to consistency of the information provided. A summary of process issues raised in these preliminary discussions is provided in Table 4.

### Table 4.—Information Process Issues and Suggestions Raised by HMOs and Other Interviewees

**A. Updated and Revised HCFA Materials:**
- Revise applications to explicitly state requirements.
- Establish clean copies of background materials; update as necessary; and tab.

**B. Improve Timeliness of Communications Relative to HMO Operational Requirements:**
1. **Accretion and Deletion Issues**
   - Improve timeliness and accuracy of information and data exchanged between Social Security Administration, HCFA, and authorized vendors.
   - Improve timeliness, accuracy, and exchange of data used to determine specific categories of beneficiaries.
   - Review Reply Listing and Exception Detail codes for accuracy, currency, and completeness prior to disseminating.
   - Change timing of Reply Listing to be 1 week earlier.
   - Disseminate DRG tape timely.
   - Communicate changes affecting Medicare claims process timely; summarize changes in one place.
   - Inform HMOs as soon as an overpayment or underpayment is discovered or suspected.
   - Disseminate OPLs as we release or receive them.

2. **Payment Issues**
3. **Dissemination of Operational Policy Letters (OPLs).**
4. **Timeliness of Communications and Responses.**

5. **HMOs’ Ability to Reach HCFA Staff**
- Provide detailed information on the ACR review process, including delineation of rationale for steps and the detail behind each step.
- Provide the methodology for how study factors are derived.
- Provide a description of how capitation rates are developed and calculated.
- Proved explicit instructions up-front on the information HMOs must submit, including the information requirements of reviewers.
- Provide explicit directions for how ACR information should be formatted (for example, using LOTUS–DOS).
- Provide acceptable and unacceptable data sources and methodologies.
- Publish alternative “recommended” studies.
- Provide guidelines for Medicare risk point of service premium calculations.
- Provide national demographic cost factors for utilization in the APR.
- Inform HMOs on a regular basis of the status of ACR submissions in the review process.
- Release benchmark data (for example, congestive heart failure and percentage of Medicare beneficiaries on ACE inhibitors) and access measures (for example, sentinel events, such as inpatient admission that should not occur if quality ambulatory care is provided).
- Provide, under the HEDIS® 3.0 (Health Plan Employer Data and Information Set), information to HMOs.
- Develop clearer standards and reviewer guidelines for Quality Improvement studies.
- Disseminate CHDR and Beneficiary Information Tracking System (BIIS) reports to all plans.
- Provide information on our organizational structure and key contacts, by operational area, with e-mail addresses and telephone numbers.
- Provide information on conferences where staff are scheduled to discuss specific issues.
- Provide information about activities and new initiatives such as the Reengineering Application and Monitoring (RAM) initiative on an on-going basis.
- Inform HMOs when staff will be out of the office, and identify a back-up person in his or her absence.
- Provide guidelines for coordination of dual eligibles and how best to serve the special needs populations.
- Disseminate to HMOs any information disseminated to other participants in Medicare risk program, for example, hospitals, physicians, beneficiaries.

6. **Bi-Annual Review**

**C. Consistency and Coordination:**
- Provide information to HMOs, at regular intervals, as new approaches are being developed.
- Strive to have structure in place prior to implementation of policies, regulations, and/or guidelines.
- Establish clean copies of background materials; update as necessary; and tab.
- Revise applications to explicitly state requirements.
- Establish clean copies of background materials; update as necessary; and tab.
- Inform HMOs on a regular basis of the status of ACR submissions in the review process.
- Release benchmark data (for example, congestive heart failure and percentage of Medicare beneficiaries on ACE inhibitors) and access measures (for example, sentinel events, such as inpatient admission that should not occur if quality ambulatory care is provided).
- Provide, under the HEDIS® 3.0 (Health Plan Employer Data and Information Set), information to HMOs.
- Develop clearer standards and reviewer guidelines for Quality Improvement studies.
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- Inform HMOs when staff will be out of the office, and identify a back-up person in his or her absence.
- Provide guidelines for coordination of dual eligibles and how best to serve the special needs populations.
- Disseminate to HMOs any information disseminated to other participants in Medicare risk program, for example, hospitals, physicians, beneficiaries.
TABLE 4.—INFORMATION PROCESS ISSUES AND SUGGESTIONS RAISED BY HMOs AND OTHER INTERVIEWEES—Continued

D. Simplifying Information Processes and Requirements:

1. Designating HMO-specific and Corporate Medicare Liaisons.
4. Streamline Marketing Approval Process

E. Coordination with Contractors:

• Identify a “point” person to answer questions about the status of the development of new, and the updating of existing, policies or regulations.
• Allow HMOs to designate an HMO-specific and corporate liaison.
• Carbon copy designated Medicare liaison on all communications.
• Designate appropriate “boilerplate” sections of the application.
• Strive to make Medicare beneficiary eligibility a real-time, on-line activity.
• Allow HMOs to maintain system logs for documentation.
• Institute a national “use and file” policy.
• Provide sufficient training to our contractors and reviewers who perform functions, such as the ACR review, PRO review, and on-site quality monitoring before allowing such agents to perform these functions.
• Improve communication between HCFA, the PROs, and CHDR; clarify respective roles of HCFA, PROs, CHDR, and HMOs.

In addition, a number of potential ways that we could communicate information to Medicare risk contract HMOs has been identified. It is likely that the most effective communication strategies may be different for Medicare risk HMOs with different characteristics and that we may want to develop multiple communication strategies to ensure that information is provided appropriately to all Medicare HMOs. Table 5 describes communication strategies that we have identified during preliminary discussions with program participants.

TABLE 5.—SUMMARY OF MAJOR RECOMMENDATIONS

A. Communication Strategy:

1. Written Materials .

• Written materials should be clear and complete; changes made to updated policies, regulations, and manuals should be explicit.
• Materials should be organized to ensure that all written materials on a specific topic are available in one place and/or are cross-referenced with other related materials.
• One contact point should be designated for HMOs to identify and request all written materials that are available. This could be on the HCFA Website, with a dedicated e-mail address or an 800 number specifically for ordering written materials.
• We should move towards providing timely written responses to outstanding inquiries and issues currently answered verbally. Currently, HMOs find the need to maintain extensive documentation of verbal communications. The use of e-mail would facilitate this.
• Currently, HMOs believe that they are not well informed of the status of our various activities (not all HMOs are members of the American Association of Healthcare Plans (AAHP) or have access to outside counsel or government affairs programs in Washington, D.C.) and it is easy to lose track of the initiatives over time because of sporadic communications.
• We should create and disseminate a newsletter which could provide timely and concise information on our activities, such as initiatives, demonstrations, and pilot programs, as well as the status of regulatory developments, that may offer HMOs opportunities to participate or may affect their operations.

—Most HMOs would be willing to pay to receive a newsletter that provided them with information and understanding of our initiatives and regulations.

• HMOs would like one person assigned to serve as their contact person for the coordination of all activities and for seeking clarification to questions.
• We should update our voice mail to indicate absences, and designate an appropriate back-up person with the authority to answer questions.
• We should set up a telephone hotline that HMOs could access to receive clarification and consistent answers to specific regulatory or operational issues.
• We should develop a fax-on-demand service to provide up-to-date information on hot topics, as the Agency for Health Care Policy and Research and provider associations have done.
• We should create written materials that are available. This could be on the HCFA Website, with a dedicated e-mail address or an 800 number specifically for ordering written materials.
• We should move towards providing timely written responses to outstanding inquiries and issues currently answered verbally.
• HMOs would like us to make beneficiary eligibility a real-time, on-line activity that would improve the timeliness and accuracy of our data and enable Medicare beneficiaries to be enrolled sooner. They would like to be able to show a log for documentation rather than paper copies in a file.
• We should move towards accepting the electronic file transfer of draft marketing materials. This procedure would permit us to make changes directly in the document, and return them to the HMOs in a timely manner, and produce documentation of comments and approval.
• HMOs support our collection of ACRs on-line, noting this was a pilot project in 1996 that will be mandatory in 1997. However, not all plans received the relevant documentation or received it after their ACRs had been submitted. Some HMOs attempting the electronic submission were unsuccessful in doing so, because of the system freezing or designated passwords not working. HMOs believe strongly that, before making a new procedure mandatory, we should first test the system to ensure it works and then disseminate the information in a timely manner prior to implementation.
• Implement a mechanism(s) for systematically tracking various HMO materials in review. Most useful to be able to track are:
III. Discussion

Under section 4002 of the Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33), and with the implementation of the Medicare+Choice program, all HMOs and CMPs will contract with us under requirements of the Medicare+Choice program. Our preliminary discussions of information needs, information process, and communication strategies have produced a significant number of issues that will be considered in the development of our Medicare risk contract HMO communication strategy.

Although the preliminary research was conducted before the BBA, the results are applicable to the Medicare+Choice program. However, since only a relatively small number of HMOs and other organizations have participated in...
this preliminary process, we are seeking additional comments and suggestions on these issues. Respondents should prioritize issues raised in the preliminary research and identify additional areas of information needs and communication strategies. In addition, it would be useful to obtain comments on issues that would be most likely to improve the effectiveness and efficiency of the Medicare risk contract program in order to establish priorities and develop a program to implement the communication strategy. This notice seeks comments and suggestions related to these issues, that we may use to develop and refine communications with Medicare risk contract HMOs.

IV. Regulatory Impact Statement

We have examined the impacts of this notice as required by Executive Order 12866 and the Regulatory Flexibility Act (Public Law 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects; distributive impacts; and equity). The Regulatory Flexibility Act (RFA) requires agencies to analyze options for regulatory relief for small businesses. Most HMOs are small entities, either by nonprofit status or by having revenues of $5 million or less annually. For purposes of the RFA, HMOs are considered small entities.

Section 1102(b) of the Social Security Act requires us to prepare a regulatory impact analysis for any rule that may have a significant impact on the operations of a substantial number of small rural hospitals. Such an analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside a metropolitan Statistical Area and has fewer than 50 beds.

Preliminary research on the information needs of Medicare risk contract HMOs and effective communication strategies has identified a number of areas in which we could provide additional information to HMOs and has identified potential strategies for communicating that information more effectively. The purpose of this notice is to seek public comments on the information needs of Medicare risk contract HMOs and communication strategies that could improve the effectiveness and efficiency of the risk contract program. For these reasons, we are not preparing an analysis for either the RFA or section 1102(b) of the Act because we have determined, and we certify, that this notice would not have a significant impact on a substantial number of small entities or a significant impact on the operations of a substantial number of small rural hospitals.

In accordance with the provisions of Executive Order 12866, this notice was not reviewed by the Office of Management and Budget.

V. Response to Comments

Because of the large number of items of correspondence we normally receive on Federal Register documents published for comment, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and the time specified in the DATES section of this preamble, and, if we proceed with a subsequent document, we will respond to the comments in that document.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance Program)


Nancy Ann Min DeParle,
Administrator, Health Care Financing Administration.

[FR Doc. 98–5234 Filed 3–4–98; 8:45 am]
BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Current List of Laboratories Which Meet Minimum Standards To Engage in Urine Drug Testing for Federal Agencies, and Laboratories That Have Withdrawn From the Program

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services notifies Federal agencies of the laboratories currently certified to meet standards of Subpart C of Mandatory Guidelines for Federal Workplace Drug Testing Programs (59 FR 29916, 29925). A similar notice listing all currently certified laboratories will be published during the first week of each month, and updated to include laboratories which subsequently apply for and complete the certification process. If any listed laboratory’s certification is totally suspended or revoked, the laboratory will be omitted from updated lists until such time as it is restored to full certification under the Guidelines.

If any laboratory has withdrawn from the National Laboratory Certification Program during the past month, it will be included as such at the end of the current list of certified laboratories, and will be omitted from the monthly listing thereafter.

This Notice is now available on the internet at the following website: http://www.health.org.

FOR FURTHER INFORMATION CONTACT: Mrs. Giselle Hersh or Dr. Walter Vogl, Division of Workplace Programs, Room 13A–54, 5600 Fishers Lane, Rockville, Maryland 20857; Tel.: (301) 443–6014.

SUPPLEMENTARY INFORMATION:

Mandatory Guidelines for Federal Workplace Drug Testing were developed in accordance with Executive Order 12564 and section 503 of Public Law 100–71. Subpart C of the Guidelines, “Certification of Laboratories Engaged in Urine Drug Testing for Federal Agencies,” sets strict standards which laboratories must meet in order to conduct urine drug testing for Federal agencies. To become certified an applicant laboratory must undergo three rounds of performance testing plus an on-site inspection. To maintain that certification a laboratory must participate in a quarterly performance testing program plus periodic, on-site inspections.

Laboratories which claim to be in the applicable stage of certification are not to be considered as meeting the minimum requirements expressed in the HHS Guidelines. A laboratory must have its letter of certification from SAMHSA, HHS (formerly: HHS/NIDA) which attests that it has met minimum standards.

Laboratories which meet the minimum standards set forth in the Guidelines:

Alliance Laboratory Services 3200 Burnet Ave., Cincinnati, OH 45229, 513–569–2051
American Medical Laboratories, Inc., 14225 American Medical Labs Drive, Lakeville, MD 21762; Tel.: (301) 443–6014
Associated Regional and University Pathologists, Inc. (ARUP), 500 Chipeta

\[FR Doc. 98–5234 Filed 3–4–98; 8:45 am\]
BILLING CODE 4120–01–P