References

The following references are on display in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. *Washington Legal Foundation* v. *Henney*, No. 99–5304, 2000 WL 122099, slip op. (D.C. Cir. February 11, 2000).

2. *Washington Legal Foundation* v. *Henney*, No. 99–5304, transcript of oral argument, January 10, 2000.

Dated: March 9, 2000.

Jane E. Henney,

Commissioner of Food and Drugs.

[FR Doc. 00–6422 Filed 3–10–00; 4:15 pm]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–3427]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration, HHS. In compliance with the requirement of section 3506(c)(2)(A) of the paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Extension of a currently approved collection; *Title of Information Collection:* End Stage Renal Disease Application and Survey and Certification Report and Supporting Regulations in 42 CFR 405.2100—405.2184; *Form No.;* HCFA–3427 (OMB# 0938–0360); *Use;* Part I of this form is a facility identification and screening measurement used to initiate the certification and recertification of ESRD facilities, Part II is completed by the Medicare/Medicaid State survey agency to determine facility compliance with ESRD conditions for coverage; *Frequency:* Annually; *Affected Public:* State, local or tribal government; *Number of Respondents:* 3740; *Total Annual Responses:* 675; *Total Annual Hours:* 1626.25.

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. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards, Attention: Julie Brown, Room N2–14–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: February 28, 2000.

John P. Burke III,

Reports Clearance Officer, HCFA Office of Information Services Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 00–6523 Filed 3–15–00; 8:45 am]

BILLING CODE 4120–03–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Study Regarding Shortages of Licensed Pharmacists

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: The ''Healthcare Research and Quality Act of 1999'', enacted on December 6, 1999, requires the Department of Health and Human Services (HHS) to ''conduct a study to determine whether and to what extent there is a shortage of licensed pharmacists.'' The Department will include in this study a summary of comments from interested public and private entities. The Department invites all interested public and private entities to submit comments on specific issues, including data and studies supporting their comments.

DATES: Comments must be submitted by May 1, 2000.

ADDRESSES: Address all comments concerning this notice to Vincent C. Rogers, D.D.S., M.P.H., Associate Administrator, Bureau of Health Professions, Health Resources and Services Administration, Room 8–05, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857.

SUPPLEMENTARY INFORMATION: On December 6, 1999, Congress enacted the Healthcare Research and Quality Act of 1999, Pub. L. 106–129, to amend title IX of the Public Health Service Act by revising and extending the Agency for Healthcare Policy and Research (now referred to as the Agency for Healthcare Research and Quality). Section 5 of Pub. L. 106–129 requires the Secretary of Health and Human Services (HHS), through the appropriate agencies of the Public Health Service, to conduct a study ''to determine whether and to what extent there is a shortage of licensed pharmacists' and to report back to Congress in one year after the date of enactment of the Act on its findings.

A number of associations, such as the National Association of Chain Drug Stores, have been voicing concerns that a shortage of pharmacists in some areas of the country might create a major health crisis. HHS invites comments from public and private sources on the following topics related to pharmacy shortages. Please address your comments by number as indicated below. You need not address all topics.

1. Shortage of pharmacists; for example, vacancy rates for pharmacists' jobs over time, existing documentation of delayed store openings or reduction in store hours, existing documentation of signing bonuses and other hiring incentives, and increases in wages;

2. Difficulties that communities may be experiencing in accessing pharmacy services. HHS is particularly interested in difficulties confronting those in rural or underserved areas, services for the elderly, and other evidence of unmet needs due to a shortage of pharmacists;

3. How pharmacies and employers are addressing a shortage of pharmacists;.

4. The use of technicians, and State laws governing ratios of pharmacists to technicians, and limitations on the functions technicians are permitted to perform, and any requirements for technician certification;

5. The impact of the growth of managed care and third-party coverage of prescriptions on pharmacy practice;

6. Problems or adverse events connected with a shortage of pharmacists, *e.g.,* medication errors;

7. The impact a drug benefit for the Medicare population might have on prescription volume and the demand for pharmacists;

8. Uses of automation or technology to assist pharmacists, such as the use of electronic transmission of prescriptions, methods of streamlining dispensing processes, and technologies that may be under development to improve efficiency of pharmacists in their duties;

9. The impact of Internet and mail order pharmacies on the demand for pharmacists; and

10. Existing information on the current pharmacist education process; in particular, applications to pharmacy programs, the impact that the shift to the doctor of pharmacy as the first professional degree may have on pharmacy supply, trends in graduates taking residencies, and students' job preferences.

Dated: March 9, 2000.

Claude Earl Fox,

Administrator.

[FR Doc. 00–6427 Filed 3–15–00; 8:45 am]

BILLING CODE 4160–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Publication of the OIG Compliance Program Guidance for Nursing Facilities

AGENCY: Office of Inspector General (OIG), HHS.

ACTION: Notice.

SUMMARY: This **Federal Register** notice sets forth the recently issued Compliance Program Guidance for Nursing Facilities developed by the Office of Inspector General (OIG). The OIG has previously developed and published compliance program guidance focused on several other areas and aspects of the health care industry. We believe that the development and issuance of this compliance program guidance for nursing facilities will continue to serve as a positive step toward promoting a higher level of ethical and lawful conduct throughout the entire health care industry.

FOR FURTHER INFORMATION CONTACT: Nicole C. Hall, Office of Counsel to the Inspector General, (202) 619–2078.

SUPPLEMENTARY INFORMATION:

Background

The creation of compliance program guidances is a major initiative of the OIG in its effort to engage the private health care community in combating fraud and abuse. In the last several years, the OIG has developed and issued compliance program guidances directed at the following segments of the health care industry: the hospital industry; home health agencies; clinical laboratories; third-party medical billing companies; the durable medical equipment, prosthetics, orthotics and supply industry; hospices; and Medicare+Choice organizations offering coordinated care plans. The development of these types of compliance program guidances is based on our belief that a health care provider can use internal controls to more efficiently monitor adherence to applicable statutes, regulations and program requirements.

Copies of these compliance program guidances can be found on the OIG web site at http://www.hhs.gov/oig.

Developing Compliance Program Guidance for Nursing Facilities

On December 18, 1998, the OIG published a solicitation notice seeking information and recommendations for developing formal guidance for nursing facilities (63 FR 70137). In response to that solicitation notice, the OIG received 16 comments from various outside sources. We carefully considered those comments, as well as previous OIG publications, such as other compliance program guidances and Special Fraud Alerts, in developing a compliance program guidance for nursing facilities. In addition, we have taken into account past and recent fraud investigations conducted by the OIG's Office of Investigations and the Department of Justice, and have consulted with the Health Care Financing Administration. In an effort to ensure that all parties had a reasonable opportunity to provide input into a final product, the draft guidance for nursing facilities was published in the **Federal Register** on October 29, 1999 (64 FR 58419) for further comments and recommendations.

Elements for an Effective Compliance Program

This compliance guidance for nursing facilities contains seven elements that the OIG has determined to be fundamental to an effective compliance program:

- implementing written policies, procedures and standards of conduct;
- designating a compliance officer and compliance committee;
- conducting effective training and education;
- developing effective lines of communication;
- enforcing standards through well-publicized disciplinary guidelines;
- conducting internal monitoring and auditing; and
- responding promptly to detected offenses and developing corrective action.

These elements are contained in previous guidances issued by the OIG. As with previously-issued guidances, this compliance program guidance represents the OIG's suggestions on how nursing facilities can best establish internal controls and prevent fraudulent activities. The contents of this guidance should not be viewed as mandatory or as an exclusive discussion of the advisable elements of a compliance program; the document is intended to present voluntary guidance to the industry and not represent binding standards for nursing facilities.

Office of Inspector General's Compliance Program Guidance for Nursing Facilities

I. Introduction

The Office of Inspector General (OIG) of the Department of Health and Human Services (DHHS) continues in its efforts to promote voluntarily implemented compliance programs for the health care industry.[1] This compliance guidance is intended to assist nursing facilities [2] develop and implement internal controls and procedures that promote adherence to applicable statutes and regulations of the Federal health care programs [3] and private insurance

[1] The OIG1 has issued compliance program guidances for the following seven industry sectors: hospitals, clinical laboratories, home health agencies, durable medical equipment suppliers, third-party medical billing companies, hospices, and Medicare+Choice organizations offering coordinated care plans. Over the next year, the OIG plans to issue compliance guidances for ambulance companies and individual and small group physician practices.

[2] For the purpose of this guidance, the term ''nursing facility'' includes a skilled nursing facility (SNF) and a nursing facility (NF) that meet the requirements of sections 1819 and 1919 of the Social Security Act (Act), respectively, 42 U.S.C. 1395i–3 and 42 U.S.C. 1396r. Where appropriate, we distinguish between SNFs and other nursing facilities.

[3] The term ''Federal health care programs'' includes any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States Government (*i.e.*, via programs such as Medicare, Federal Employees Health Benefits Act, Federal Employees' Compensation Act, Black Lung, or the Longshore and Harbor Worker's Compensation Act) or any State health plan (*e.g.*, Medicaid, or a program receiving funds from block grants for social services

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