DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

Centers for Disease Control and Prevention

42 CFR Part 493

[HSQ–233–P]

CLIA Program; Cytology Proficiency Testing

AGENCY: Health Care Financing Administration (HCFA) and Centers for Disease Control and Prevention (CDC), HHS.

ACTION: Proposed rule.

SUMMARY: In this proposal, HHS is complying with a court order requiring publication of a proposed rule to require that cytology proficiency testing (PT) be conducted, to the extent practicable, under normal working conditions. In accordance with the court order, we are proposing to revise regulations that implement the Clinical Laboratory Improvement Amendments of 1988 (CLIA) to require that PT be conducted at a pace corresponding to the maximum workload rate for individuals examining cytology slides. As a separate matter, we use this opportunity to solicit comments on the use of computer facsimile representations of cytology specimens, as an alternative to glass slide PT.

DATES: Comments will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on January 29, 1996.

ADDRESSES: Mail written comments (1 original and 3 copies) to the following address: Centers for Disease Control and Prevention, Attention: HSQ–233–P, 4770 Buford Hwy, N.E., MS F11, Atlanta, Ga. 30341–3724.

If you prefer, you may deliver your written comments (1 original and 3 copies) to the following address: Room 309–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code HSQ–233–P. Comments received timely will be available for public inspection as they are received 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).

For comments that relate to information collection requirements, mail a copy of comments to: Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Allison Herron Eydt, HCFA Desk Officer.

FOR FURTHER INFORMATION CONTACT: Rhonda S. Whalen, (770) 488–7670.

SUPPLEMENTARY INFORMATION:

I. Background

Under section 353 of the Public Health Service Act (42 U.S.C. 263a), which embodies provisions of the Clinical Laboratory Improvement Amendments of 1988 (CLIA), all laboratories that examine human specimens for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of, human beings must meet certain requirements to perform the examination. On February 28, 1992 (57 FR 7002), we published regulations to implement CLIA at 42 CFR part 493, with most sections of the regulations effective September 1, 1992. On January 14, 1993, plaintiffs, the Consumer Federation of America and Public Citizen, filed a lawsuit in the United States District Court for the District of Columbia, challenging the Department of Health and Human Services' implementation of CLIA (*Consumer Federation of America and Public Citizen* v. *HHS,* Civil Action No. 93–97 (D.D.C.)). As one aspect of their complaint, plaintiffs argued that the regulations violated the requirements of the law by failing to require cytology proficiency testing (PT) ''to the extent practicable, under normal working conditions.''

On August 29, 1995, the court ruled that the regulations did not strictly conform to the statute. The court ruled that, within 90 days of this order, we publish proposed regulations in the Federal Register, in accordance with 42 U.S.C. 263a(f)(4)(B)(iv) regarding proficiency testing of cytologists, to ensure that cytologists are tested, to the extent practicable, under normal working conditions, and request public comment. The court further ruled that we are to issue a final rule regarding the same within a reasonable time thereafter. As provided in the court's August 29 ruling, the PT regulations promulgated by the Department on February 28, 1992, remain in effect pending the issuance of the final PT regulations required by the court. It should be noted that this particular notice only addresses matters in the court order pertaining to cytology PT, and it is not designed to respond to a separate part of the court order pertaining to test classification and personnel standards.

II. Proposed Rule

In this proposed rule, we are complying with that portion of the court order requiring the publication of proposed regulations and solicitation of public comment to ensure that PT of cytology personnel is conducted, to the extent practicable, under normal working conditions. We note, however, that the Department of HHS has filed a notice of appeal with respect to the order. If the order is reversed on appeal, we would still review the comments and carefully consider the appropriate course of action.

The current PT regulations are based on the principle that effective and appropriate PT should not be equated to the routine examination of patient specimens. Nevertheless, in accordance with the court's ruling, we are soliciting comments on a proposal to change the current regulations (which authorize the examination of PT slides at a rate of five slides per hour), to require the examination of PT slides at a new rate, which is set at the maximum workload rate of 12.5 slides per hour. To achieve this PT workload rate, in this rule, we are proposing to change the amount of time allowed for completion of the PT examination from 2 hours to 45 minutes, while retaining the same number of slides (10) per test. (For a 20-slide PT retest, the test time would change from 4 hours to 90 minutes.)

We recognize that there may be other options for complying with the court order requiring that PT be conducted under normal working conditions. One option for consideration to comply with the order would be to maintain the current 2-hour testing time period but increase the number of slides per PT examination (in other words, require the examination of 25 slides in a 2-hour period and, for a retest, require 50 slides to be examined in a 4-hour period). We are cautious about supporting this alternative because we have concerns about the practical feasibility of obtaining sufficient referenced slides for a nationally-administered 25-slide test set for PT; however, we are interested in receiving comments on this option. Another option would be to specify that PT be conducted at each individual's actual workload rate (which could be less than the maximum workload rate) for examining patient slides. We recognize that this alternative will present problems in administering PT but are interested in receiving comments on the appropriateness of such a proposal, together with