part 71) modifies Class E airspace at Monticello, IN to accommodate aircraft executing the GPS Runway 18 SIAP and the GPS Runway 36 SIAP at White County Airport. Controlled airspace extending upward from 700 to 1200 feet AGL is needed to contain aircraft executing the approach. The area will be depicted on appropriate aeronautical charts thereby enabling pilots to circumnavigate the area or otherwise comply with IFR procedures.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this regulation—(1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

# PART 71—[AMENDED]

1. The Authority citation for 14 part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120, E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389; 14 CFR 11.69.

# §71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9D, Airspace Designations and Reporting Points, dated September 4, 1996, and effective September 16, 1996, is amended as follows:

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

\* \* \* \* \*

AGL IN E5 Monticello, IN [Revised] White County Airport, IN

(Lat. 40°42'32" N, long. 86°46'00" W)
That airspace extending upward from 700 feet above the surface within a 6.4-mile radius of White County Airport and within

2.7 miles each side of the  $185^\circ$  bearing from the airport extending from the 6.4-mile radius to 7.4 miles south of the airport.

Issued in Des Plaines, Illinois on February 5, 1997.

Maureen Woods,

Manager, Air Traffic Division. [FR Doc. 97–4069 Filed 2–18–97; 8:45 am]

BILLING CODE 4910-13-M

## 14 CFR Part 73

[Airspace Docket No. 96–AGL–16] RIN 2120–AA66

Amendment to Time of Designation for Restricted Area R-4305, Lake Superior, MN

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Final rule.

SUMMARY: This rule amends the time of designation for Restricted Area 4305 (R–4305), Lake Superior, MN, by reducing the requirement for the issuance of a Notice to Airmen (NOTAM) from 12 hours in advance to 4 hours in advance of activation of the airspace. The U.S. Air Force requested this amendment to permit greater flexibility in scheduling R–4305.

**EFFECTIVE DATE:** 0901 UTC, May 22, 1997.

# **FOR FURTHER INFORMATION CONTACT:** Steve Brown, Airspace and Rules

Steve Brown, Airspace and Rules Division, ATA–400, Office of Air Traffic Airspace Management, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone: (202) 267–8783.

#### SUPPLEMENTARY INFORMATION:

## History

On November 5, 1996, the FAA proposed to amend Title 14 of the Code of Federal Regulations part 73 (14 CFR part 73) to amend the time of designation for R-4305 from the current "Intermittent by NOTAM, 12 hours in advance," to "Intermittent by NOTAM, 2 hours in advance." (61 FR 56927). Interested parties were invited to participate in this rulemaking proceeding by submitting written comments on the proposal to the FAA. No comments objecting to the proposal were received. However, the FAA determined that 2 hours advance notice did not allow enough time for the NOTAM to be processed and still have adequate lead time for airspace users to become aware of the activation prior to their flights. Therefore, the time of designation will now read: "Intermittent by NOTAM, 4 hours in advance." The

FAA's Great Lakes Region coordinated this change with the regional U.S. Air Force representative and, on January 27, 1997, the U.S. Air Force formally accepted the modification to their proposal. Except for editorial changes and the time of designation change from "Intermittent by NOTAM, 2 hours in advance" to "Intermittent by NOTAM, 4 hours in advance," this amendment is the same as that proposed in the notice. Section 73.43 of part 73 of the Federal Aviation Regulations was republished in FAA Order 7400.8D dated July 11, 1996.

## The Rule

This amendment to part 73 of the Federal Aviation Regulations (14 CFR part 73) amends the time of designation for R–4305 from the current "Intermittent by NOTAM, 12 hours in advance," to "Intermittent by NOTAM, 4 hours in advance." The current 12-hour in advance NOTAM requirement does not permit the using agency sufficient flexibility to efficiently accomplish its mission in the event of maintenance or weather delays, or other operational factors. This action will not alter the existing boundaries, altitudes, or designated purpose of R–4305.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) Is not a "significant regulatory action" under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

#### **Environmental Review**

This action will not affect the existing boundaries, altitudes, or activities conducted in R–4305. There will be no change from current operations and no new air traffic procedures will be necessary as a result of this rule. Therefore, the FAA has determined that this action is not subject to environmental assessments and procedures in accordance with FAA Order 1050.1D, "Policies and Procedures for Considering Environmental Impacts."

List of Subjects in 14 CFR Part 73 Airspace, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 73 as follows:

# PART 73—[AMENDED]

1. The authority citation for part 73 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389; 14 CFR 11.69.

#### §73.43 [Amended]

## R-4305 Lake Superior, MN [Amended]

By removing "Time of Designation. Intermittent by NOTAM, 12 hours in advance," and substituting "Time of designation. Intermittent by NOTAM, 4 hours in advance."

Issued in Washington, DC, on February 7, 1997.

Jeff Griffith,

Program Director for Air Traffic Airspace Management.

[FR Doc. 97–4068 Filed 2–18–97; 8:45 am] BILLING CODE 4910–13–P

# DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Office of Inspector General

42 CFR Part 1008

RIN 0991-AA85

Medicare and State Health Care Programs: Fraud and Abuse; Issuance of Advisory Opinions by the OIG

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

**ACTION:** Interim final rule with comment period.

SUMMARY: In accordance with section 205 of the Health Insurance Portability and Accountability Act of 1996, this final rule establishes a new part 1008 in 42 CFR chapter V to address the new OIG advisory opinion process. Specifically, these regulations set forth the specific procedures by which the Office of Inspector General, in consultation with the Department of Justice, will issue advisory opinions to outside parties regarding the interpretation and applicability of certain statutes relating to the Medicare and State health care programs.

**DATES:** Effective Date: This rule is effective on February 21, 1997.

Comment Period: To assure consideration, public comments must be

delivered to the first address provided under ADDRESSES by no later than 5 p.m. on April 21, 1997. Comments will be available for public inspection March 5, 1997 at the second address provided under ADDRESSES on Monday through Friday of each week from 8:00 a.m. to 4:30 p.m., (202) 619–0089.

ADDRESSES: Please mail or deliver your written comments to the following address: Office of Inspector General, Department of Health and Human Services, Attention: OIG-10-IFC, Room 5246, Cohen Building, 330 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 OIG-10-IFC.

FOR FURTHER INFORMATION CONTACT: Joel Schaer, (202) 619–0089, OIG Regulations Officer.

## SUPPLEMENTARY INFORMATION:

I. Background

A. The Medicare Anti-Kickback Statute

Section 1128B(b) of the Social Security Act (42 U.S.C. 1320a–7b(b)) provides criminal penalties for individuals or entities that knowingly and willfully offer, pay, solicit or receive remuneration in order to induce business reimbursed under the Medicare or State health care programs. The offense is classified as a felony, and is punishable by fines of up to \$25,000 and imprisonment for up to 5 years.

This provision is quite broad. The types of remuneration covered specifically include kickbacks, bribes, and rebates, whether made directly or indirectly, overtly or covertly, or in cash or in kind. In addition, prohibited conduct includes not only remuneration intended to induce referrals of patients, but remuneration intended to induce the purchasing, leasing, ordering, or arranging for any good, facility, service, or item paid for by Medicare or State health care programs.

Since the statute on its face is so broad, concern has been expressed for many years that some relatively innocuous commercial arrangements are technically covered by the statute and are, therefore, subject to criminal prosecution.

#### B. Safe Harbors and Fraud Alerts

As a response to the above concern, the Medicare and Medicaid Patient and Program Protection Act of 1987, Public Law 100–93, specifically required the development and promulgation of regulations, the so-called "safe harbor" provisions, designed to specify various

payment and business practices which, although potentially capable of inducing referrals of business under the Medicare and State health care programs, would not be treated as criminal offenses under the anti-kickback statute (section 1128B(b) of the Social Security Act; 42 U.S.C. 1320b(b)) and would not serve as a basis for a program exclusion under section 1128(b)(7) of the Social Security Act; 42 U.S.C. 1320a–7(b)(7).

The OIG safe harbor provisions have been developed to permit individuals and entities to freely engage in business practices and arrangements that encourage competition, innovation and economy. Health care providers and others may voluntarily seek to comply with these provisions so that they have the assurance that their business practices are not subject to any enforcement action under the antikickback statute or program exclusion authority. The 13 final safe harbor provisions, which specify practices which are expressly made legal, are codified at 42 CFR 1001.952.

In addition, the OIG has also periodically issued Special Fraud Alerts to give continuing guidance to health care providers with respect to practices the OIG regards as unlawful. Eight individual Special Fraud Alerts were published in the Federal Register on December 19, 1994 (59 FR 65372), August 10, 1995 (60 FR 40847) and June 17, 1996 (61 FR 30623). Thus, for many years the OIG has been publishing substantial guidance indicating what practices are lawful and what practices the OIG considers unlawful under the anti-kickback statute.

# C. Advisory Opinions: Section 205 of Public Law 104–191

The Health Insurance Portability and Accountability Act of 1996, Public Law 104-191, effective August 21, 1996, now requires the Department to provide additional formal guidance regarding the application of the anti-kickback statute and the safe harbor provisions, as well as other OIG health care fraud and abuse sanctions. Among the provisions set forth in section 205 of Public Law 104–191 is the requirement that the Department, in consultation with the Department of Justice (DoJ), issue written advisory opinions to particular parties with regard to: (1) What constitutes prohibited remuneration under the anti-kickback statute; (2) whether an arrangement or proposed arrangement satisfies the criteria in section 1128B(b)(3) of the Social Security Act, or established by regulation, for activities which do not result in prohibited remuneration; (3) what constitutes an inducement to