Department of Health and Human Services
Office of Inspector General
Office of Audit Services

December 2025 | A-04-22-04086

Florida Retina Institute Generally Met Medicare Requirements for Ophthalmology Services Provided on the Same Day as Eye Injections

REPORT HIGHLIGHTS

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Florida Retina Institute Generally Met Medicare Requirements for Ophthalmology Services Provided on the Same Day as Eye Injections

Why OIG Did This Audit

- Prior OIG work found that Medicare inappropriately paid for services that were billed as being unrelated to, distinct from, or significant and separately identifiable from injections of drugs into the eye (i.e., intravitreal injections) or other services provided on the same day.

- Our analysis showed that the Florida Retina Institute (FRI) frequently billed for ophthalmology services provided on the same day as intravitreal injections, and its billing patterns were similar to those found in previous OIG audits that identified improper billing for ophthalmology services.

- This audit assessed whether FRI complied with Medicare requirements when billing for ophthalmology services provided on the same day as an intravitreal injection during calendar years 2020 and 2021.

What OIG Found

- FRI generally complied with Medicare requirements when billing for ophthalmology services provided on the same day as intravitreal injections. For 92 of the 100 sampled patient days, FRI complied with Medicare requirements for all services billed; for 8 sampled patient days it did not. Specifically, FRI incorrectly billed Medicare for services that were not medically necessary and not separately identifiable from the intravitreal injection.

- We estimated that Medicare made overpayments totaling at least $42,295 to FRI for ophthalmology services that did not comply with Medicare requirements.

- The overpayments in our sample occurred because FRI did not fully implement its policy of monitoring its claims process to promptly identify deficiencies that would affect the accuracy of its claims.

What OIG Recommends

We recommended FRI refund the $42,295 in Medicare overpayments. Although FRI disagreed with our findings, they concurred with our recommendation.

TABLE OF CONTENTS

INTRODUCTION

WHY WE DID THIS AUDIT

Medicare Part B reimburses physicians for intravitreal injections that are reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. [1, 2] Medicare may also reimburse physicians for other services (e.g., diagnostic imaging services) provided on the same day as an intravitreal injection if the services are unrelated to, distinct from, or significant and separately identifiable from the injection.[3]

During calendar years 2020 and 2021 (audit period), Medicare paid approximately $597.9 million for intravitreal injections and $484.3 million for evaluation and management (E/M) and other services provided on the same day as the injections.[4, 5] Prior Office of Inspector General (OIG) audits and evaluations found that Medicare made inappropriate payments for: (1) E/M services that were billed on the same day as intravitreal injections but were not significant and separately identifiable from the injections; and (2) other services that were billed as being unrelated to, or distinct from, the intravitreal injections or other services provided on the same day. See Appendix B for a list of related OIG reports.

This audit is the last in a series of audits of ophthalmology services. We analyzed 2019 Medicare data to identify ophthalmologists at risk for noncompliance with Medicare billing requirements for ophthalmology services provided on the same day as intravitreal injections. The Florida Retina Institute (FRI) was identified for audit because it frequently billed for other services as being unrelated to, distinct from, or significant and separately identifiable from intravitreal injections.

[1] An intravitreal injection is an ophthalmology procedure that places medication directly into the space in the back of the eye, called the vitreous cavity, to treat medical conditions such as wet age-related macular degeneration. The procedure is usually performed by a trained retina specialist in an office setting. Wet age-related macular degeneration occurs when abnormal blood vessels begin to grow underneath the retina and leak blood or fluid that blurs central vision.

[2] Social Security Act (The Act) § 1862(a)(1)(A).

[3] The Act § 1848(c)(1)(A)(ii); 42 CFR § 414.40(b)(1); National Correct Coding Initiative (NCCI) Policy Manual, chapter I, § E. See also The Centers for Medicare & Medicaid Services (CMS's) Medicare Claims Processing Manual (The Manual), Pub. No. 100-04, chapter 12, §§ 40.1(A), 40.1(B), and 40.1(C).

[4] Physicians and nonphysician practitioners perform E/M services to assess and manage a beneficiary's health. For the purposes of our audit, "other services" does not include the medication the ophthalmologist administered through the intravitreal injection.

[5] This was the most recent data available at the start of the audit.

OBJECTIVE

Our objective was to determine whether FRI complied with Medicare requirements when billing for ophthalmology services provided on the same day as an intravitreal injection procedure.

BACKGROUND

Medicare Program

Title XVIII of the Act established the Medicare program, which provides health insurance coverage to people aged 65 and over, people with disabilities, and people with end-stage renal disease. CMS administers the program. CMS contracts with Medicare Administrative Contractors (MACs) to process and pay Medicare Part B claims. Medicare Part B provides supplementary medical insurance for medical and other health services when they are medically necessary, including coverage of services provided by ophthalmologists. When billing for covered services, medical providers must also comply with Medicare billing requirements.

Ophthalmology Services and Intravitreal Injections

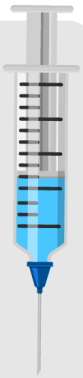
Ophthalmology is the branch of medicine concerned with the study and treatment of disorders and diseases of the eye. Ophthalmology services include intravitreal injections of medication to treat eye diseases such as wet age-related macular degeneration.

Medicare pays for intravitreal injections as part of a global surgery payment that includes the preoperative, intraoperative, and postoperative services provided by the physician (see Figure 1).[6]

E/M services provided on the same day as intravitreal injections are usually included in the payment for the injections. The patient's initial consultation with the physician or the

Figure 1: Global Surgery Payments

The Global Surgery Payment for an Intravitreal Injection Includes:



- **Preoperative Services**
  The initial consultation or evaluation of the problem by the physician to determine the need for surgery made on the same day as the surgery
- **Intraoperative Services**
  Services that are normally a usual and necessary part of a surgical procedure
- **Postoperative Services**
  Followup services during the postoperative period of the surgery that are related to recovery from the surgery

[6] The Act § 1848(c)(1)(A)(ii); 42 CFR §§ 410.20(a) &(b)(1) and 414.40(b)(1). The 2020 and 2021 Medicare Physician Fee Schedules indicate that the procedure code for an intravitreal injection (HCPCS 67028) has a global surgery period of "000", which is defined as a minor surgery (NCCI Policy Manual, chapter I, § D; 84 Federal Register 62568 (Nov. 15, 2019); 85 Federal Register 84472 (Dec. 28, 2020)).

physician's evaluation of the problem to determine the need for surgery is always included in the payment for an intravitreal injection.[7]

Medicare may make a separate payment for other services (e.g., diagnostic imaging services) provided by the same physician on the same day as the surgery if the services are unrelated to, distinct from, or significant and separately identifiable from the surgery.[8] To identify such services, Medicare requires that certain modifiers be included on claims. These modifiers allow Medicare claims to bypass automated prepayment edits in a MAC's claims processing system, which are designed to prevent improper payment when certain procedure codes are submitted together.[9] For example, an edit would identify and disallow services that are generally included in the global surgery payment.

Two examples of these modifiers are the following:

- **Modifier 25** indicates that a service was for a significant, separately identifiable E/M service that was above and beyond the other service provided or beyond the usual preoperative and postoperative care associated with the procedure.[10, 11, 12]

[7] The Act § 1848(c)(1)(A)(ii); 42 CFR § 414.40(b)(1); NCCI Policy Manual for Medicare Services, chapter I, § D. See also The Manual, Pub. No. 100-04, chapter 12, §§ 30.6.6, 40.1(A), 40.1(B), and 40.1(C).

[8] The Act § 1848(c)(1)(A)(ii); 42 CFR § 414.40(b)(1); NCCI Policy Manual, chapter I, § E. See also, The Manual, Pub. No. 100-04, chapter 12, §§ 40.1(A), 40.1(B), and 40.1(C).

[9] An edit is programming within the standard claim processing system that: (1) selects certain claims; (2) evaluates or compares information on the selected claims or other accessible sources; and (3) acts on the claims—depending on the evaluation—such as paying claims in full or in part, denying payments, or suspending claims for manual review.

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[12] American Medical Association (AMA), *Current Procedural Terminology (CPT) Professional Code Book*. NCCI Policy Manual, chapter I, § D, § E.1.b.

- **Modifier XU** indicates that a service was distinct because it did not overlap usual components of the main service.[13]

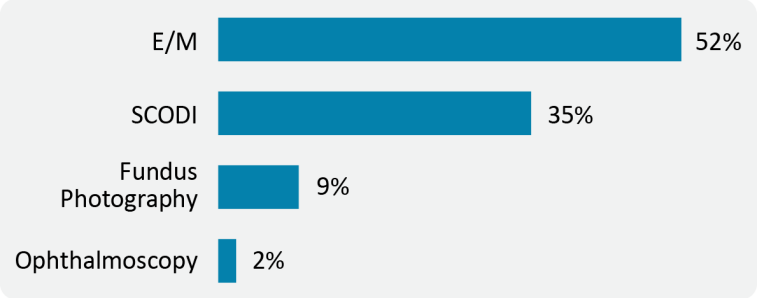
A modifier may be appended to a procedure code only if the clinical circumstances justify the use of the modifier. A modifier may not be appended to a procedure code solely to bypass an edit if the clinical circumstances do not justify its use.[14] The intravitreal injection and the separately payable services must be appropriately and sufficiently documented in the patient's medical record to support the claim for these services.[15]

Florida Retina Institute

FRI has 20 locations throughout Central Florida, North Florida, and Southeast Georgia. FRI was established in 1979 and consists of 15 board-certified ophthalmologists who are fellowship-trained vitreoretinal surgeons that provide comprehensive patient care in vitreous and retinal ophthalmology.[16]

Our data analysis showed that FRI billed for other services on the same day as an intravitreal injection 95 percent of the time during our audit period. Medicare paid FRI approximately $3.3 million for the intravitreal injections and approximately $3.1 million for E/M and other services, including Scanning Computerized Ophthalmic Imaging (SCODI), Fundus Photography, and Ophthalmoscopy. These four services accounted for 98 percent of Medicare payments made to FRI for services provided on the same day as the injections (see Figure 2).

Figure 2: Medicare Payments for Other Services Provided on the Same Day as Intravitreal Injections



SCODI is a non-invasive imaging technique that produces high-resolution images of the retina. **Fundus photography** is a procedure that uses a retinal camera to photograph regions of the eye for diagnostic purposes. **Ophthalmoscopy** is an examination of the back part of the eye.

[13] AMA, *CPT Professional Code Book*. NCCI Policy Manual, chapter I, § E.1e.

[14] NCCI Policy Manual, chapter I, § E.1.

[15] The Act § 1833(e).

[16] A vitreoretinal surgeon is an ophthalmologist specializing in the surgical and medical treatment of conditions affecting the vitreous, the gel-like substance filling the eye, and the retina, the light-sensitive tissue at the back of the eye.

HOW WE CONDUCTED THIS AUDIT

Our audit covered $6,243,445 in Medicare payments to FRI for 34,060 patient days with intravitreal injections and E/M or other services provided on the same day during our audit period.[17, 18] We selected a stratified random sample of 100 patient days with payments totaling $20,274 and consisting of 317 services for review.

We obtained copies of medical records from FRI as support for the services provided on the sampled patient days. We then provided those records to an independent medical review contractor to determine whether the medical records supported that the services were unrelated to, distinct from, or significant and separately identifiable from intravitreal injections or other services provided on the same day.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Appendix A contains our audit scope and methodology, Appendix B contains a list of related OIG reports, Appendix C contains our statistical sampling methodology, and Appendix D contains our sample results and estimates.

FINDINGS

FRI generally complied with Medicare requirements when billing for ophthalmology services provided on the same day as an intravitreal injection procedure. FRI complied with Medicare requirements for all services billed for 92 of the 100 sampled patient days. However, FRI did not comply with Medicare requirements for all services billed for 8 sampled patient days for which Medicare paid FRI $414. Specifically, FRI incorrectly billed Medicare for services that were not medically necessary (six patient days) and not separately identifiable from the intravitreal injection (two patient days).

These errors occurred because FRI did not fully implement its monitoring policy that required it to conduct monitoring of its claims process to promptly identify deficiencies that would affect the accuracy of its claims. On the basis of our sample results, we estimated that FRI received overpayments totaling at least $42,295 for ophthalmology services that did not meet Medicare requirements.

[17] A patient day consists of all Medicare paid services for a specific patient on a specific day provided by FRI, except for the medication used in the intravitreal injection.

[18] We removed patient days with dates of service that were previously reviewed by a CMS contractor and for which Medicare was not the primary payor.

FLORIDA RETINA INSTITUTE RECEIVED MEDICARE PAYMENTS FOR SOME OPHTHALMOLOGY SERVICES THAT DID NOT MEET MEDICARE REQUIREMENTS

FRI received Medicare payments for ophthalmology services for 8 sampled patient days that did not meet Medicare requirements. Six patient days contained services that were not medically necessary, and two patient days contained E/M services that were not separately identifiable from the intravitreal injections.

Services Not Medically Necessary

Medicare covers fundus photography, intravitreal injection, and SCODI services that are performed on the same day when the services are reasonable and necessary.[19]

Fundus Photography

Fundus photography is a procedure involving the use of a retinal camera to photograph regions of the eye for diagnostic purposes. Fundus photography and SCODI are generally mutually exclusive of one another, in that an ophthalmologist would use one technique or the other to evaluate fundal disease.[20] A limited number of clinical conditions exist where both techniques are medically reasonable and necessary. In these situations, both services may be claimed by appending a modifier XU on the fundus service.

For four sampled patient days, FRI billed fundus photography services with a modifier XU, indicating that the patients' clinical conditions necessitated both fundus photography and SCODI. However, our independent medical review contractor determined that the medical necessity of the fundus photography was not supported by the patient's medical record. In all four instances, the medical record did not explain why FRI needed to perform both fundus photography and SCODI at the same visit. FRI was overpaid $134 for these services.

For example, in one instance the medical record documented that the fundus photographs were for the purpose of an initial evaluation; however, the decision to perform the intravitreal injection was primarily based on the physician's interpretation of the SCODI results. The fundus photographs did not contribute to the decision to perform the intravitreal injection. As such, the fundus photographs were not necessary to guide in the management of the patient's condition.

[19] The Act §1862(a)(1)(A)).

[20] First Coast Service Options Local Coverage Determination (LCD) – Fundus Photography (L33670). Fundal disease generally refers to diseases or conditions affecting the back of the eye. These conditions can lead to various visual impairments, including blurred vision, visual field defects, and even blindness if not diagnosed and treated promptly.

Intravitreal Injection

An intravitreal injection is an ophthalmology procedure that places medication directly into the space in the back of the eye to treat eye diseases.

For one sampled patient day, our independent medical review contractor found that FRI billed for an intravitreal injection in the patient's right eye, but the patient's medical record did not support the medical necessity of the procedure. Specifically, the medical review contractor found that the physician's retinal evaluation and diagnostic testing (i.e., macular imaging and fundus photographs) demonstrated that there was no active swelling, accumulation of fluid beneath the retina, or fluid leakage or bleeding in the right eye. Therefore, the intravitreal injection of medication into the patient's right eye was not medically necessary. FRI was overpaid $82 for this service.

Scanning Computerized Ophthalmic Diagnostic Imaging

SCODI is a non-invasive imaging technique that produces high-resolution images of the retina. It is used to diagnose and treat conditions of the eye, such as wet aged-related macular degeneration, macular edema, and diabetic retinopathy.[21] No more than one SCODI examination per month is considered medically reasonable and necessary to manage a patient undergoing active treatment.[22]

For one sampled patient day, our independent medical review contractor found that FRI performed a SCODI examination more often than monthly. FRI performed the SCODI examination during the patient's visit on the sampled patient day; however, the patient's medical record showed that FRI performed a SCODI examination during the patient's visit 21 days prior. Therefore, the SCODI examination performed on the sampled patient day was not medically necessary. FRI was overpaid $31 for this service.

Evaluation and Management Services Not Separately Identifiable from Intravitreal Injections

E/M services are cognitive services in which physicians or other qualified healthcare professionals diagnose and treat illness or injury.[23] The physician's decision to perform a minor surgical procedure (such as intravitreal injections) is included in the payment for the procedure

[21] Macular edema is when the macula, the central part of the retina, swells due to fluid buildup. Diabetic retinopathy is caused by high blood sugar levels that damage blood vessels in the retina.

[22] First Coast Service Options Local Coverage Determination (LCD) – Scanning Computerized Ophthalmic Diagnostic Imaging (SCODI) (L33751).

[23] Physicians' cognitive services involve the application, based on relevant knowledge and experience, of such skills as data gathering and analysis, planning, management, decision-making, and judgment relating to the prevention, diagnosis, and treatment of health problems, and communication of such information to the patient.

and must not be reported separately as an E/M service.[24] An E/M service should only be billed on the same day if a significant and separately identifiable E/M service is rendered and clearly documented in the patient's medical record.[25]

Providers should append modifier 25 to the appropriate E/M code when billing Medicare to indicate the patient's condition required a significant, separately identifiable E/M service.[26] Providers should not use modifier 25 to report E/M services that resulted in a decision to perform the minor surgical procedure, nor should they use the modifier solely to bypass automated prepayment edits in the MAC's claims processing system if the clinical circumstances do not justify its use.[27]

For two sampled patient days, FRI appended a modifier 25 to the billed E/M service. However, our independent medical review contractor found that the E/M service was not significant and separately identifiable from the intravitreal injection, as there were no new diagnoses, symptoms, or visual issues compared to the previous visit that would justify additional evaluation or testing. FRI was overpaid $167 for these services.

FLORIDA RETINA INSTITUTE DID NOT FULLY IMPLEMENT ITS CLAIMS MONITORING POLICY

FRI's policies and procedures for medical record documentation, correct coding, billing, and claims submission are documented in its written policies. The policies require FRI to conduct quarterly, bi-annual, and annual monitoring of its claims process to promptly identify deficiencies that would affect the accuracy of its claims. However, FRI did not perform these reviews as frequent as their policy required. During our two-year audit period, FRI conducted five billing and medical chart reviews that identified and corrected deficiencies like those found by our independent medical reviewers in our sample.

FRI officials said they did not fully implement the monitoring policy due to staffing shortfalls caused by the COVID-19 pandemic. FRI officials stated that they have been in compliance with their monitoring schedule since April 2023. FRI's full implementation of its claims monitoring policy should further decrease the possibility of it improperly billing ophthalmology services on the same day as intravitreal injections.

[24] NCCI, Chapter I, § D.

[25] The Act § 1833(e); 42 CFR § 424.5(a)(6); and NCCI, Chapter I, §§ D & E.

[26] AMA, CPT Professional Code Book, Appendix A (modifier 25).

[27] NCCI, Chapter I, §§ D & E.

ESTIMATE OF OVERPAYMENT

On the basis of our sample results, we estimated that Medicare overpaid FRI at least $42,295 for ophthalmology services provided on the same day an intravitreal injection that did not meet Medicare requirements.

RECOMMENDATION

We recommend that the Florida Retina Institute refund to the Federal Government the estimated $42,295 in Medicare overpayments for services improperly billed.[28]

FLORIDA RETINA INSTITUTE COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, FRI concurred with our recommendation to refund the Federal Government $42,295 in Medicare overpayments but generally disagreed with our findings. Specifically, FRI disputed our finding that it did not comply with Medicare requirements for eight sampled patient days, including services it billed as medically necessary or not separately identifiable from intravitreal injections. FRI also expressed concerns about the adequacy of CMS guidance on E/M and other services provided on the same day as intravitreal injections.

FRI's comments, excluding Attachment A, are included in their entirety as Appendix E.[29]

FRI COMMENTS

Regarding our recommendation, FRI said it would refund the Federal Government $42,295 to demonstrate good faith cooperation with the OIG. However, FRI generally disagreed with our findings. To support its position, FRI engaged an expert to analyze sample patient days to provide a view on medical necessity and the appropriateness of billing under Medicare requirements. The expert's view was that the medical records for all eight sampled patient days document medically necessary and appropriately billed services. FRI stated that while the expert examined two patients in detail, FRI believes the remaining patient records similarly

[28] OIG audit recommendations do not represent final determinations by Medicare. CMS, acting through a MAC or other contractor, will determine whether overpayments exist and will recoup any overpayments consistent with its policies and procedures. Providers have the right to appeal those determinations and should familiarize themselves with the rules pertaining to when overpayments must be returned or are subject to offset while an appeal is pending. The Medicare Part A and Part B appeals process has five levels (42 CFR § 405.904(a)(2)), and if a provider exercises its right to an appeal, the provider does not need to return overpayments until after the second level of appeal. Potential overpayments identified in OIG reports that are based on extrapolation may be re-estimated depending on CMS determinations and the outcome of appeals.

[29] FRI hired an expert and included the expert's opinion as an attachment. Because FRI included its concerns regarding the medical necessity and appropriateness of billing Medicare requirements in the body of its comments, we excluded the attachment from this report. FRI's comments, including the attachment, will be provided to CMS.

document the medical necessity of the services. FRI provided this analysis as an attachment to its response.

FRI also stated that despite the OIG's largely favorable findings regarding FRI's general compliance with Medicare requirements, it has enduring concerns that CMS has provided physicians with insufficient guidance about the agency's standards and expectations for billing E/M and other services on the same day as intravitreal injections. FRI stated that it continues to implement compliance measures to ensure that separately billed E/M services are clearly significant and separately identifiable. It also said it continues to apply its good faith interpretation of the limited available guidance to support what it considers to be appropriate billing of E/M services.

OFFICE OF INSPECTOR GENERAL RESPONSE

We acknowledge FRI's concurrence with our recommendation to refund the Federal Government $42,295 in Medicare overpayments and its willingness to demonstrate good faith cooperation.

We reviewed FRI's comments and the analysis it submitted in response to our findings. While we recognize FRI's position and the analysis provided, we maintain that our findings are supported by the medical record documentation reviewed by our independent medical review contractor during the audit.

We also acknowledge FRI's concerns regarding the sufficiency of guidance from CMS related to billing E/M services on the same day as intravitreal injections. However, evaluating CMS's guidance was outside the scope of our audit. Our review focused solely on whether FRI complied with existing Medicare requirements when billing for ophthalmology services, including E/M services, on the same day as intravitreal injections.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

We identified 34,060 patient days totaling $6,243,445 in Medicare payments to FRI for intravitreal injections and other services provided on the same day during our audit period. This included patient days with dates of service within our audit period that were not previously reviewed by a CMS contractor and for which Medicare was the primary payor. From these patient days we selected a stratified random sample of 100 patient days with payments totaling $20,274 for review.

We did not review FRI's overall internal control structure. Rather, we limited our review of internal controls to those that were significant to our objective. This includes reviewing FRI's management oversight structure, and its established policies, procedures, and processes for controlling and monitoring compliance with Medicare requirements for intravitreal injections and other services provided on the same day.

METHODOLOGY

To accomplish our objective, we took the following steps:

- reviewed applicable Federal laws, regulations, and guidance;
- held discussions with CMS and MAC officials to obtain an understanding of Medicare reimbursement requirements for intravitreal injections and other services provided on the same day as the intravitreal injections;
- held discussions with FRI officials to obtain an understanding of their policies and procedures for providing, documenting, and billing intravitreal injections and other ophthalmology services provided on the same day;
- used CMS National Claims History file to identify Medicare paid claims for intravitreal injections and other services provided by FRI on the same day during calendar years (CYs) 2020 and 2021;
- identified a sampling frame of 34,060 patient days that consisted of all Medicare payments to FRI for intravitreal injections and other services provided on the same day (except for the medication used in the intravitreal injection);
- selected a stratified random sample of 100 patient days with payments totaling $20,274 for review (see Appendix C);

- reviewed data from CMS's Common Working File for the claims included in the sample to determine whether the claims had been canceled or adjusted;

- reviewed data from the Recovery Audit Contractor Data Warehouse for the claims included in the sample to determine whether the claims had been previously reviewed;

- obtained medical records from FRI for the patient days in our sample and provided the documentation to an independent medical review contractor who determined whether each sample item complied with Medicare requirements;

- reviewed and summarized the independent medical reviewer contractor's results;

- estimated the amount in the sampling frame that Medicare overpaid FRI during our audit period for intravitreal injections and other ophthalmology services provided on the same day that did not comply with Medicare requirements (see Appendix D); and

- discussed the results of our audit with FRI officials.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

APPENDIX B: RELATED OFFICE OF INSPECTOR GENERAL REPORTS

Report Title	Report Number	Date Issued
An Ophthalmology Clinic in Florida: Audit of Medicare Payments for Eye Injections of Avastin, Eylea, and Lucentis	A-09-19-03025	9/7/2021
An Ophthalmology Clinic in California: Audit of Medicare Payments for Eye Injections of Eylea, and Lucentis	A-09-19-03022	3/29/2021
Medicare Paid $22 Million in 2012 for Potentially Inappropriate Ophthalmology Claims	OEI-04-12-00281	12/22/2014
Fletcher Allen Health Care Did Not Always Bill Correctly for Evaluation and Management Services Related to Eye Injection Procedures	A-01-11-00515	5/21/2012
Use of Modifier 59 to Bypass Medicare's National Correct Coding Initiative Edits	OEI-03-02-00771	11/25/2005

APPENDIX C: STATISTICAL SAMPLING METHODOLOGY

SAMPLING FRAME

Our sampling frame consisted of 34,060 patient days totaling $6,243,445 in Medicare payments to FRI for intravitreal injections and other services provided on the same day during CYs 2020 and 2021. The frame included patient days with dates of service within our audit period that were not previously reviewed by a CMS contractor and for which Medicare was the primary payor.

SAMPLE UNIT

The sample unit was a patient day.

SAMPLE DESIGN AND SAMPLE SIZE

We used a stratified random sample as shown in Table 1.

Table 1: Details of Sampling Frame

Stratum	Value of Patient Day	Number of Frame Units	Sample Size	Dollar Value of Frame Units
1	$0–$170.95	16,540	34	$2,102,328
2	$170.96–239.10	9,732	33	2,038,216
3	$239.11–$778.24	7,788	33	2,102,901
Totals		**34,060**	**100**	**$6,243,445**

SOURCE OF RANDOM NUMBERS

We generated the random numbers using the OIG, Office of Audit Services (OAS), statistical software.

METHOD OF SELECTING SAMPLE ITEMS

We sorted the patient days in each stratum by a unique identifier and then consecutively numbered the patient days in each stratum. After generating the random numbers according to our sample design, we selected the corresponding frame items for review.

ESTIMATION METHODOLOGY

We used the OIG/OAS statistical software to estimate the total improper payment amount in the sampling frame that Medicare made to FRI for intravitreal injections and other services provided on the same day during CYs 2020 and 2021. To be conservative, we recommended

recovery of improper payments at the lower limit of a two-sided 90-percent confidence interval. Lower limits calculated in this manner are designed to be less than the actual improper payment total 95 percent of the time.

APPENDIX D: SAMPLE RESULTS AND ESTIMATES

Table 2: Sample Details and Results

Stratum	Number of Patient Days in Frame	Value of Patient Days in Frame	Sample Size	Number of Services in Sample	Value of Sample	Number of Patient Days with Unallowable Services in Sample	Value of Unallowable Services in Sample
1	16,540	$2,102,328	34	71	$4,099	1	$31
2	9,732	2,038,216	33	112	6,869	1	61
3	7,788	2,102,901	33	134	9,306	6	322
Total	**34,060**	**$6,243,445**	**100**	**317**	**$20,274**	**8**	**$414**

Table 3: Estimated Value of Unallowable Services in the Sampling Frame
(Limits Calculated for a 90-Percent Confidence Interval)

Point estimate	$109,305
Lower limit	42,295
Upper limit	176,315

ROPES & GRAY LLP
2099 PENNSYLVANIA AVENUE, NW
WASHINGTON, DC 20006-6807
WWW.ROPESGRAY.COM

October 10, 2025

Hall, Margaux
T +1 202 508 4811

VIA EMAIL

Truman M. Mayfield
Regional Inspector General for Audit Services
Office of Inspector General
Office of Audit Services, Region IV
61 Forsyth Street, SW, Suite 3T41
Atlanta, GA 30303
Truman.Mayfield@oig.hhs.gov

Re: Response to HHS-OIG Draft Report for Florida Retina Institute (Report A-04-22-04086)

Dear Mr. Mayfield:

On behalf of Florida Retina Institute (FRI), I hereby respond to the Department of Health and Human Services Office of Inspector General (HHS-OIG) request for comments concerning the HHS-OIG recommendations in the September 2025 draft report titled *Florida Retina Institute Generally Met Medicare Requirements for Ophthalmology Services Provided on the Same Day As Eye Injections* (Report). Thank you for the opportunity to review the Report.

FRI is pleased that HHS-OIG found that FRI complied with Medicare requirements for all services billed for 92 of the 100 sampled patient days and that FRI complied with Medicare requirements when billing for ophthalmology services provided on the same day as an intravitreal injection procedure. FRI concurs with these findings.

At the same time, FRI generally disagrees with HHS-OIG's finding that FRI did not comply with Medicare requirements for all services billed for eight sampled patient days for which Medicare paid FRI a total of $414. FRI further disagrees with the finding that FRI incorrectly billed Medicare for services that were not medically necessary on six patient days and not separately identifiable from the intravitreal injection on two patient days. After receiving your draft audit findings, FRI engaged an expert to analyze sampled patient days to provide a view on medical necessity and the appropriateness of billing under Medicare requirements. That expert's analysis is provided in Attachment A and reflects the expert's view that the medical records for all eight sampled patient

days document medically necessary and appropriately billed services.[1] FRI requests that HHS-OIG review the responses provided in Attachment A – that Attachment A documents the reasons FRI believes its billing was appropriate in these sampled cases. **Notwithstanding FRI's objections to the findings, as discussed in Attachment A, in order to demonstrate its good faith cooperation with HHS-OIG, FRI agrees to concur** and refund the Federal Government the estimated $42,295.

FRI also raises with HHS-OIG its continuing view that the Centers for Medicare & Medicaid Services (CMS) should provide appropriate, fulsome guidance on the billing requirements for evaluation and management (E/M) services on the same day as intravitreal injections. FRI continues to implement compliance measures to ensure that separately billed E/M services are clearly significant and separately identifiable. FRI employs its good faith interpretation of the limited available guidance to support what it believes to be appropriate billing of E/M services. **Notwithstanding HHS-OIG's largely favorable findings regarding FRI's general compliance with Medicare requirements, FRI has enduring concerns that CMS has provided physicians with insufficient guidance about the agency's standards and expectations for billing E/M and other services on the same day as intravitreal injections**. In this regard, FRI supports HHS-OIG's May 2025 audit report recommendation that CMS clarify Medicare requirements for billing E/M services provided on the same day as intravitreal injections,[2] in order to enable providers to understand the agency's view of appropriate use of modifier 25. FRI has taken note of recent CMS guidance,[3] which provides some – but, in its view, incomplete – instruction about select scenarios in this specialized clinical area. A lack of adequate agency guidance has contributed to uncertainty among providers regarding CMS's view of permissible billing of "significant and separately identifiable" E/M services. FRI urges CMS to offer clear, complete guidance in this area.

Please feel free to reach out with any questions.

Very truly yours,

Margaux J. Hall

Margaux Hall

[1] While the expert examined two patients in detail in Attachment A, FRI believes the remaining patient records similarly document the medical necessity of the services provided and billed to Medicare.

[2] *See* U.S. Dep't of Health & Human Servs., Office of Inspector Gen., *Medicare Payments for E&M Services Provided on the Same Day as Intravitreal Injections*, A-09-23-03014 (May 2025).

[3] *See* Ctrs. for Medicare & Medicaid Servs., *Evaluation and Management Services*, MLN006764 (Sept. 2025).

cc:
Donna J. Stephenson
Senior Auditor
Donna.stephenson@oig.hhs.gov

Scott Perry
Assistant Regional Inspector General for Audit Services
Scott.Perry@oig.hhs.gov

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330 Independence Ave., SW
Washington, DC 20201

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