Telehealth During 2020 Helped Ensure End-Stage Renal Disease Patients Received Care, But Limited Information Related to Telehealth Was Documented

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OFFICE OF AUDIT SERVICES FINDINGS AND OPINIONS

The designation of financial or management practices as questionable, a recommendation for the disallowance of costs incurred or claimed, and any other conclusions and recommendations in this report represent the findings and opinions of OAS. Authorized officials of the HHS operating divisions will make final determination on these matters.
• Glossary of Terms (slide 4)
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Dialysis Access Site: Dialysis access is the way to reach the blood during dialysis for cleaning and filtering. The site would be the location of the dialysis access on the patient’s body.

End-Stage Renal Disease (ESRD): A medical condition in which a person's kidneys permanently cease functioning, leading to the need for a regular course of long-term dialysis or a kidney transplant to maintain life.

ESRD-Related Services: Most outpatient dialysis-related physician services that manage a patient on dialysis, whether the patient receives dialysis treatments at-home or in-center.

Interactive Telecommunications System: A piece of multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner.

Non-Public-Facing Technology: A remote communication product that, as a default, allows only the intended parties to participate in the communication, such as a video chat application allowing only the provider and patient to participate.
Why We Did This Audit

• In response to the COVID-19 public health emergency (PHE) and pursuant to section 1135 of the Social Security Act, the Secretary of Health and Human Services (HHS) authorized the Centers for Medicare & Medicaid Services (CMS) to temporarily implement waivers and modifications to Medicare program requirements, retroactive to March 2020.

• From March through December 2020 (audit period), Medicare claims data shows that payments for ESRD-related telehealth services increased almost 10,000 percent from 2019.

• Oversight of telehealth expansion is increasingly important to ensure that Medicare enrollees receive the appropriate care while protecting the program from fraud, waste, and abuse.

• We conducted this audit of ESRD-related telehealth services provided during the first year of the PHE to verify whether providers complied with Medicare requirements, determine what telehealth-related information was documented in the medical records, and further inform policymakers and other stakeholders as they consider permanent changes to telehealth policies.
Our objectives were to determine, for ESRD-related telehealth services provided during the PHE: (1) what information related to the telehealth services was documented in the medical records and (2) whether the claims met certain Medicare requirements.
The Medicare ESRD program is a national health insurance program for people with ESRD and covers all services under Medicare, not only those related to kidney failure.

To stay alive, ESRD patients need (1) a kidney transplant or (2) a regular course of long-term dialysis, which can be provided in a dialysis facility (in center) or at home.

ESRD patients also receive other ESRD-related services beyond dialysis, such as dialysis planning and prescription, health, dietary, and transplant assessments.
Before the PHE, ESRD-related services for in-center and at-home patients were originally added to the list of approved Medicare telehealth services in 2005 and 2017, respectively. Relevant Medicare requirements for ESRD-related telehealth services before the PHE were:

1. For both in-center and at-home patients, the eligible patient’s location at the time the service was furnished, known as the “originating site,” was limited to rural health professional shortage areas or counties that were not included in a metropolitan statistical area, and did not include a patient’s place of residence. However for at-home patients, the patient’s place of residence was added as an originating site and the geographic restrictions were removed beginning January 1, 2019, but only for the purposes of the required clinical examination of the dialysis access site furnished through telehealth.

2. The telehealth service must be provided using an interactive telecommunication system that included audio and video (audiovisual) technology permitting two-way, real-time interactive communication between the patient and physician or practitioner, not audio-only.

3. The required clinical examination of the dialysis access site must have been furnished in person without the use of an interactive telecommunications system.

4. The clinical examination of the dialysis access site was also required to be furnished in person monthly for in-center patients and for at-home patients was required to be furnished in person monthly for the first 3 months of home dialysis and once every 3 consecutive months thereafter.

1 See slide 12 for the specific ESRD-related service codes.
Background: Telehealth Services *During* the Public Health Emergency

During the PHE, section 1135(b)(8) of the Social Security Act authorized CMS to waive or modify telehealth requirements. As a result, CMS issued the 2020 Interim Final Rule entitled *Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency* (final rule) which temporarily implemented waivers and modifications to certain Medicare program requirements.

- On March 1, 2020, CMS started paying for telehealth services, including office, hospital, and other visits furnished by physicians and other practitioners to patients located anywhere in the country, including in a patient's place of residence.

- The final rule changed Medicare payment regulations so that physicians and other practitioners would be allowed “broad flexibilities to furnish services using remote communications technology to avoid exposure risks to health care providers, patients, and the community.”

- CMS did not issue any specific telehealth documentation requirements. Rather, CMS expected the *same level of documentation* that would ordinarily be provided if the services furnished via telehealth were conducted in person.

Telehealth During 2020 Helped Ensure ESRD Patients Received Care, But Limited Information Related to Telehealth Was Documented
Regarding ESRD-related services during the PHE, CMS waived the requirement for the clinical examination of the dialysis access site to be furnished in person and began allowing it to be furnished as a Medicare telehealth service.²

- CMS did not waive the requirement for telehealth services to use an interactive telecommunication system. ESRD-related telehealth services during the PHE were still required to be provided using interactive audiovisual technology, not audio-only.

- CMS did not waive the required frequency of the dialysis access site exam, which was monthly for in-center patients and for at-home patients was monthly for the first 3 months of home dialysis followed by once every 3 consecutive months.

² CMS was authorized to waive the requirement for the clinical examination of the dialysis access site to be furnished in person by various sources. Section 1135(b)(8) of the Social Security Act authorized CMS to implement the waiver for in-center patients, and section 3705 of the Coronavirus Aid, Relief, and Economic Security Act authorized the waiver for at-home patients.
Medicare requires that to provide telehealth via live video, health care providers must use video communication products in a manner that is compliant with the Health Insurance Portability and Accountability Act (HIPAA) of 1996 Privacy and Security Rules (45 CFR Parts 160 and 164). HHS’ Office for Civil Rights (OCR) oversees and enforces the requirements of the Privacy and Security Rules under HIPAA, not CMS.  

In April 2020, OCR issued a temporary notice that ended May 11, 2023, stating that it would exercise its enforcement discretion during the PHE and not impose penalties on covered health care providers for noncompliance with the HIPAA Rules in connection with the good faith provision of telehealth using non-public-facing remote communication product.

OCR defines a "non-public-facing" remote communication product as one that, as a default, allows only the intended parties to participate in the communication.

Any information shared in this report related to non-public-facing technology is strictly for informational purposes.

Medicare reimburses physicians or practitioners of ESRD-related services through Current Procedural Terminology (CPT) codes as follows:

- **CPT Codes 90951-90962**: age-specific and based on the number of visits per month for patients receiving dialysis in an outpatient setting (in-center).
- **CPT Codes 90963-90966**: age-specific and based on the number of visits per month for patients receiving dialysis at home.
- **CPT Codes 90967-90970**: age-specific and based on the number of visits for less than a month of service, billed per day.

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**Figure 1: ESRD-Related Service CPT Codes and Descriptions**

<table>
<thead>
<tr>
<th>Patient Age</th>
<th>In-Center Dialysis</th>
<th>At-Home Dialysis</th>
<th>In-Center or At-Home Per Diem Visits</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>4+ Visits</td>
<td>2–3 Visits</td>
<td>1 Visit</td>
</tr>
<tr>
<td>&lt;2</td>
<td>90951</td>
<td>90952</td>
<td>90953</td>
</tr>
<tr>
<td>2–11</td>
<td>90954</td>
<td>90955</td>
<td>90956</td>
</tr>
<tr>
<td>12–19</td>
<td>90957</td>
<td>90958</td>
<td>90959</td>
</tr>
<tr>
<td>20+</td>
<td>90960</td>
<td>90961</td>
<td>90962</td>
</tr>
</tbody>
</table>

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5 The five character codes and descriptions included in this document are obtained from Current Procedural Terminology (CPT®), copyright 2020–2021 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures. Any use of CPT outside of this report should refer to the most current version of the Current Procedural Terminology available from AMA. Applicable FARS/DFARS apply.
Medicare payments of approximately $2.2 billion over calendar years (CYs) 2018 through 2020 remained relatively stable for the ESRD-related service claims identified on the previous slide (CPT codes 90951 – 90970).

Medicare payments for all ESRD-related services, both telehealth and non-telehealth, remained around $740,000,000 during each year of 2018 through 2020. Once the PHE began, Medicare payments for ESRD-related services did not increase overall.
Conversely, after the PHE began, Medicare payments for ESRD-related services provided via telehealth increased by approximately 10,000 percent.

**Figure 3: Total ESRD-Related Telehealth Service Payments for CYs 2018-2020**

- CY 2018: $319,610
- CY 2019: $379,213
- CY 2020: $379,213 (increase from CY 2019)

- CY 2020: $37,902,978 (increase from CY 2019)

Telehealth During 2020 Helped Ensure ESRD Patients Received Care, But Limited Information Related to Telehealth Was Documented
Our audit covered $37,902,978 in Medicare Part B payments for 179,952 ESRD-related telehealth services provided during the period March 1 through December 31, 2020. We selected a stratified random sample with two strata:

**Figure 4: OIG Statistical Sample Strata**

- **In-Center Stratum:** Medicare enrollees receiving dialysis treatments as an outpatient in a dialysis facility
  - 75 claim lines $16,409

- **At-Home Stratum:** Medicare enrollees receiving dialysis treatments at home
  - 25 claim lines $4,909

= 100 claim lines $21,318

See Appendix A for information related to the statistical sample. We did not include the per diem CPT codes (90967 – 90970) in our sampling frame because per diem CPT codes accounted for only 3 percent of claim lines and 0.4 percent of Medicare payments in the population.
To accomplish our objectives, we:

- obtained from CMS’s Integrated Data Repository the paid Medicare Part B fee-for-service payments made to physicians and other practitioners for ESRD-related services (CPT codes 90951 through 90966) that were billed as telehealth, i.e., with either a place of service “02” or modifiers “95,” “GQ,” or “GT” and performed during our audit period;

- created a sampling frame of 179,952 claim lines totaling $37,902,978 for ESRD-related services rendered to Medicare patients receiving in-center or at-home dialysis treatments and selected a stratified random sample of 100 claim lines (see Figure 4 on the previous slide); and

- obtained supporting documentation from Medicare providers for the 100 sampled claim lines and determined whether ESRD-related services complied with Medicare requirements and what information related to telehealth was documented in the medical records.

We did not audit CMS’ overall internal control structure, only those internal controls related to our audit objectives such as CMS communication to providers on providing ESRD-related services via telehealth and on billing for ESRD-related services.
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.
Providers documented limited information in medical records related to telehealth services, but the ESRD-related telehealth service claim lines generally met certain Medicare requirements.

- Generally, the only telehealth information documented in the medical records was that the service was provided via telehealth.

- Providers generally complied with Medicare billing requirements.
Most Medical Records Identified That the ESRD-Related Services Were Provided Via Telehealth

Of the 100 sampled claim lines:

- 88 claim lines identified (using various notations; see examples shown in Table 1) that the ESRD-related services were provided via telehealth.

- 10 claim lines were billed as telehealth in error.6

- 2 claim lines were not supported with medical records for any services.7

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6 There is no financial impact of the medical records for the 10 claim lines billed telehealth in error because ESRD-related services provided via telehealth were paid at the same rate as if they were furnished in person.

7 See slide 23 for the finding related to unsupported claim lines.

<table>
<thead>
<tr>
<th>Notation</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Telehealth visit</td>
<td>24</td>
</tr>
<tr>
<td>Encounter completed with telehealth</td>
<td>18</td>
</tr>
<tr>
<td>Telehealth visit during the COVID-19 pandemic (or any mention of COVID-19)</td>
<td>13</td>
</tr>
<tr>
<td>Method of Interaction: via telehealth or Method: telehealth</td>
<td>12</td>
</tr>
<tr>
<td>Telehealth encounter using audiovisual technology, performed according to State requirements.</td>
<td>7</td>
</tr>
</tbody>
</table>
Findings:
Telehealth Service-Related Information Documented in the Medical Records (cont.)

Most Medical Records Did Not Identify the Telehealth Technology Used

- Of the 88 sampled claim lines that we confirmed were provided via telehealth, only 25 medical records identified what type of telecommunications systems were used in one or more of the telehealth visits.

- Although CMS did not establish telehealth-specific documentation requirements, medical records for 64 claim lines did not identify the type of telecommunications systems used in any of the telehealth visits. Therefore, we could not determine whether telehealth services were provided using an interactive telecommunications system using audiovisual technology that was non-public-facing.8

8 Only OCR's Telehealth Notification of Enforcement Discretion addresses non-public-facing technology and only for the purposes of OCR enforcement. CMS does not enforce this requirement.
Most Patients Received Their Dialysis Access Site Examination In Person

- Of the 98 sampled claim lines for which we received documentation representing 98 unique patients, medical records revealed that although CMS waived the requirement for the required clinical examination of the dialysis access site to be furnished in person during the PHE, most patients still received this medical examination in person.

Figure 6: What the Medical Records Revealed About the Examination of the Dialysis Access Site

*At-home patients could have had their examination outside the sampled month.*
Findings:
Telehealth Service-Related Information Documented in the Medical Records (cont.)

Many ESRD-Related Services Were Provided During Telehealth Visits

- Of the 88 sampled claim lines that we confirmed were provided via telehealth, medical records for all 88 claim lines included documentation of the ESRD-related services provided. We categorized these services based on the type of service provided.

Figure 7: The Number of Claim Lines in Which Medical Records Referenced Each Category of ESRD-Related Services

<table>
<thead>
<tr>
<th>Service</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dialysis Planning and Prescription Assessments</td>
<td>88</td>
</tr>
<tr>
<td>Health Assessments</td>
<td>84</td>
</tr>
<tr>
<td>Dietary Assessments</td>
<td>68</td>
</tr>
<tr>
<td>Transplant Assessments</td>
<td>26</td>
</tr>
</tbody>
</table>

*The total is greater than 88 because numerous claim lines had more than one category of service provided.*
Most ESRD-Related Service Sampled Claim Lines Were Allowable

Of the 100 sampled claim lines, we found:

- 2 claim lines were not supported by medical records,
- 3 claim lines were for telehealth services provided using solely audio-only technology for all telehealth visits, and
- 2 claim lines were billed using the wrong CPT code based on the number of telehealth visits.

We are not requesting recovery of these Medicare payments because the effect is immaterial.

* Two additional claim lines, in which medical records showed audio-only technology was used, were allowable because at least one other visit was conducted either in-person or using an interactive telecommunication system.
Conclusion

Providers documented limited information related to telehealth services in the medical records, but the ESRD-related telehealth service claim lines generally met certain Medicare requirements.

- Most medical records for sampled claim lines included documentation identifying that the service was provided via telehealth but did not include documentation that would allow us to determine whether the services were provided using 1) audiovisual interactive technology and 2) technology that was non-public-facing.

- Although we are not making any recommendations, we believe it would be beneficial for the medical records to document the type of telecommunications system used to perform the telehealth visit.

- This information may be beneficial to CMS and OCR when considering future oversight mechanisms or changes regarding remote communication products.

Because this report contains no recommendations, CMS did not provide written comments on our draft report but did provide technical comments, which we addressed as appropriate.
Appendix A:
Statistical Sampling Methodology

SAMPLING FRAME
The sampling frame consisted of one Excel spreadsheet containing 179,952 claim lines that met the criteria of our target population totaling $37,902,978 in payments. The target population consists of Medicare Part B fee-for-service payments made to physicians and other practitioners for ESRD-related services (CPT codes 90951 through 90966) that were billed as telehealth, i.e., with either a place of service “02” or modifiers “95”, “GQ”, or “GT”, and performed during the period of March 1 through December 31, 2020. These payments were made from the Medicare Trust Fund to physicians and other practitioners that had not been previously reviewed by OIG as of May 2, 2022.

SAMPLE UNIT
The sample unit was a claim line.

SAMPLE DESIGN AND SAMPLE SIZE
We used a stratified random sample based on whether the Medicare patient received services in center or at home. Stratum 1 included all ESRD-related services provided to patients who received dialysis treatments in center and Stratum 2 for patients who received dialysis treatments at home during the audit period.

<table>
<thead>
<tr>
<th>Stratum</th>
<th>CPT Code Type</th>
<th>Number of Frame Units</th>
<th>Frame Dollar Value</th>
<th>Sample Size</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>In-Center</td>
<td>134,953</td>
<td>29,196,515</td>
<td>75</td>
</tr>
<tr>
<td>2</td>
<td>At-Home</td>
<td>44,999</td>
<td>8,706,463</td>
<td>25</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>179,952</td>
<td>37,902,978</td>
<td>100</td>
</tr>
</tbody>
</table>

SOURCE OF RANDOM NUMBERS
We generated the random numbers using the OIG, Office of Audit Services, statistical software.

METHOD OF SELECTING SAMPLE UNITS
We sorted the claim lines in each stratum by the unique line of service identifier in ascending order and then consecutively numbered the lines in the sampling frame. After generating 100 random numbers according to our sample design, we selected the corresponding frame lines for review.
Appendix B: Regulatory and Policy Requirements

- **Social Security Act, § 1135(b)(8)**
  The Health and Human Services (HHS) Secretary is authorized to temporarily waive or modify Medicare telehealth requirements during a national emergency. This includes but is not limited to the requirement for the clinical examination of the dialysis access site of in-center patients to be furnished in person (without telehealth) during the PHE.

- **Social Security Act, § 1833(e); 42 CFR §§ 424.5(a)(6) and 494.170**
  Providers of ESRD-related telehealth services must maintain complete, accurate, and accessible records on all patients and must furnish such information, as appropriate, to determine whether payment is due and the amount of payment.

- **Social Security Act § 1881(b)(3)(B)**
  For home dialysis patients, the required clinical examination of the dialysis access site was required monthly for the first 3 months of dialysis followed by once every 3 consecutive months thereafter.

- **Coronavirus Aid, Relief, and Economic Security Act (CARES Act) § 3705**
  The CARES Act amended section 1881(b)(3)(B) of the Social Security Act by adding a new clause that allows the HHS Secretary to waive the requirement for the clinical examination of the dialysis access site of at-home patients to be furnished in person during the PHE.
Appendix B: Regulatory and Policy Requirements (cont.)

- **69 Fed. Reg. 66236, 66276 (Nov. 15, 2004)**
  CMS added ESRD-related services for in-center patients to the list of approved Medicare telehealth services. The required clinical examination of the dialysis access site must be furnished in person monthly without the use of an interactive telecommunications system.

- **80 Fed. Reg. 41686, 41783 (July 15, 2015)**
  CMS added ESRD-related services for at-home patients to the list of approved Medicare telehealth services. The required clinical examination of the dialysis access site must be furnished in person without the use of an interactive telecommunications system.

- **83 Fed. Reg. 35704, 35729 (July 24, 2018)**
  Beginning on January 1, 2019, for patients with ESRD receiving home dialysis, for purposes of the required monthly clinical assessments to examine the dialysis access site, the home of the patient was added as an originating site and the geographic restrictions were removed for telehealth services.
Appendix B: Regulatory and Policy Requirements (cont.)

- **85 Fed. Reg. 19230, 19233 (Apr. 6, 2020)**
  The final rule directed physicians and practitioners who bill for Medicare telehealth services to report the place of service code that would have been reported had the service been furnished in person and apply the CPT telehealth modifier, modifier 95, to claim lines that describe services furnished via telehealth. This allowed ESRD-related services furnished via Medicare telehealth which, if not for the PHE for the COVID-19 pandemic, would have been furnished in person, at the same rate they would have been paid if the services were furnished in person.

- **85 Fed. Reg. 19230, 19242 (Apr. 6, 2020)**
  For the duration of the PHE, CMS waived the requirement for the clinical examination of the access site to be performed in person without the use of an interactive telecommunications system.

  OCR issued a temporary notice in April 2020 stating that it would exercise its enforcement discretion during the PHE and not impose penalties on covered health care providers for noncompliance with the HIPAA Rules in connection with the good faith provision of telehealth using non-public-facing remote communication product.
Appendix B: Regulatory and Policy Requirements (cont.)

- **42 CFR 410.78(a)(3)**
  Interactive telecommunications systems are defined as multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner.

- **42 CFR 410.78(b)**
  Medicare Part B pays for covered telehealth services included on the telehealth list, including ESRD-related physician services, when furnished by an interactive telecommunications system.

- **42 CFR 410.78(b)(4) (2005)**
  The eligible patient’s location at the time the service was furnished, known as the “originating site,” was limited to rural health professional shortage areas or counties that were not included in a metropolitan statistical area, and did not include a patient’s place of residence.

- **42 CFR 414.314(a)(1)**
  ESRD-related services include all professional services furnished by a physician or practitioner except those listed at 42 CFR 414.314(b).
Medicare Claims Processing Manual (MCPM), Chapter 8, Section 140(A).
Medicare guidelines identify 18 specific types of ESRD-related physician services that could be provided during a physician’s visit.

COVID-19 Frequently Asked Questions on Medicare Fee-for-Service Billing
(originally issued 3/17/20 but then updated to add this information on 4/9/20 and 5/27/20)
There are no payment restrictions on distant site practitioners furnishing Medicare telehealth services from their home during the PHE. CMS expected the same level of documentation that would ordinarily be provided if the services furnished via telehealth were conducted in person.

Guidance to assist covered entities in complying with the HIPAA Rules when OCR’s Telehealth Notification is no longer in effect. To provide telehealth via live video, health care providers must use video communication products that are compliant with the Health Insurance Portability and Accountability Act of 1996.