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2017 OPPS AND MPFS FINAL RULES:
Minor Changes for Nuclear Medicine

According to estimates made by the Centers for Medicare & Medicaid Services (CMS) in the final rule for the hospital outpatient prospective payment system (OPPS) (issued on November 1, 2016), 2017 rates will increase by approximately 1.7 percent. A 2 percent reduction will be applied to payments of hospitals that do not meet the outpatient quality reporting requirements.

As explained below, CMS will continue several of its imaging policies with no, or slight, revisions. For 2017, it also continued the APC restructuring it started last year, which resulted in several radiology codes being moved from one APC to another. In 2017, several interventional radiology procedures have been reassigned from imaging APCs to vascular procedure APCs. However, no changes were made to the nuclear medicine APCs, and payments are provided in the table below.

Table 1: OPPS Rates for Nuclear Medicine APCs

APCs	APC Descriptions	2016 OPPS Rates	2017 OPPS Rates
5591	Level 1 nuclear medicine and related services	$332.65	$332.94
5592	Level 2 nuclear medicine and related services	$441.36	$428.95
5593	Level 3 nuclear medicine and related services	$1,108.46	$1,138.46
5594	Level 4 nuclear medicine and related services	$1,285.17	$1,320.97
5661	Level 1 nuclear medicine and related services	$249.98	$216.59

Threshold-Packaged Drugs

For 2016, the packaging threshold for establishing separate APCs for drugs, biologicals and radiopharmaceuticals was $100. For 2017, CMS has increased the threshold to $110. This means that items with a per-day cost less than or equal to $110 will be packaged, and items with a per-day cost greater than $110 are separately payable.

The payment rates for HCPCS codes for separately payable drugs and biologicals can be found in Addenda B of the final rule. (See Information Source below for link.) These rates are based on average sales price (ASP) data from the third quarter of 2016. CMS uses the most recent ASP data to update the payment rates in January 2017 and then quarterly thereafter if it receives updated manufacturer's data that shows the need.

New Radiopharmaceutical Codes

For 2017, CMS created five new "A" HCPCS Level II codes representing positron emission tomography (PET) services. As listed in Table 2, three of these will have pass-through payment status. Effective January 1, 2017, there are two other new codes for radiopharmaceuticals:

2017 Level II Codes	Descriptions
•A9597	PET radiopharmaceutical, diagnostic, for tumor identification, not otherwise classified
•A9598	PET radiopharmaceutical, diagnostic, for non-tumor identification, not otherwise classified

Addendum B of the 2017 OPPS rules shows that codes A9597 and A9598 have a status indicator of "N"—a SI assigned to most diagnostic radiopharmaceuticals. This SI indicates that CMS bundles the cost of the drug into the procedure payment rate. Even though facilities do not receive separate payment, they are encouraged to code and bill separately for these radiopharmaceuticals because, as CMS states, "All these charges play a role in defining future hospital payment."

Pass-Through Status Changes

In the 2017 hospital OPPS final rule, CMS included its end-of-the-year changes to the expiring and continuing pass-through-status codes. On the expiring side, there are 15 drugs and biologicals listed but no radiopharmaceuticals. There are 47 drugs (into which CMS includes radiopharmaceuticals) and biologicals with new or continuing pass-through payment status in 2017. The following radiopharmaceuticals are included in that number. The symbol • represents codes that are new for 2017.

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Table 2: Radiopharmaceuticals with 2017 Pass-Through Status				
2016 Codes	**2017 Codes**	**2017 Code Descriptors**	**APCs**	**Payment Rates**
C9461	C9461	Choline C 11, diagnostic, per study dose	9461	$5,700.00
NA	NA	Florbetapir F18, diagnostic, per study dose, up to 10 millicuries	9052	$2,756.00
NA	NA	Gallium Ga-68, dotatate, diagnostic, 1 mCi	9056	$ 66.74
NA	NA	Fluciclovine F18, diagnostic, 0.1 mCi	9052	$ 389.55
C9459	C9459	Flutemetamol F18, diagnostic, per study dose, up to 5 millicuries	9459	$3,135.00
C9458	C9458	Florbetaben F18, diagnostic, per study dose, up to 8.1 millicuries	9458	$2,968.00

Under the current policy, pass-through payments are made for a period of at least two years, but not more than three years. Although this policy will continue in 2017, CMS did make a slight change to, it says, "eliminate the variability of the pass-through payment eligibility period, which currently varies based on the timing of the particular application, as we now believe that the timing of a pass-through payment application should not determine the duration of pass-through payment status."

For example, a drug or biological granted pass-through status that takes effect on January 1 would receive three years of pass-through status but one with a status effective on April 1 would receive 2 ¾ years of pass-through status. One with pass-through status that took effect on July 1 would receive 2 ½ years of pass-through status; and a drug with pass-through status effective on October 1 would receive 2 years and 3 months (a quarter) of pass-through status.

Beginning with pass-through drugs and biologicals newly approved in 2017 and subsequent years, CMS will allow a quarterly expiration of pass-through payment status for drugs and biologicals to afford a pass-through period that is as close to a full three years as possible.

Modifier JW Required

Although not required for radiopharmaceuticals, the JW modifier is ***required*** effective January 1, 2017, on all Medicare claims to identify single-use drug vial waste. When billing, you ***must*** report the waste on a separate line from the patient-administered dose. Although required, implementation may vary from one Medicare administrative contractor (MAC) to another so be sure to check with your MAC for its specifics.

In Transmittal 1248 (change request 5520, issued July 2, 2007), CMS gave the following example for reporting drug waste: 58 milligrams of adenosine administered to a patient for a pharmacological stress test was taken from a 90-milligram single-use vial. The waste must be documented. It does not need to be in the report but can be on a department work/flow sheet. The provider would bill 58 units of J0153 and 32 units of J0153-JW.

More details about the modifier JW requirement can be found in the frequently asked questions (FAQs) posted by CMS at the following address: *https://www.cms.gov/Medicare/ Medicare-Fee-for-Service-Payment/ Hospital¬OutpatientPPS/Downloads/JW-Modifier-FAQs.pdf*.

Good News about PC for MPPR

In the 2017 final rule, CMS significantly modified its 2016 policy that implemented a 25 percent payment discount to the professional component (PC) of the second and subsequent advanced imaging services furnished in the same session. Effective January 1, 2017, the PC payment discount will be just 5 percent for each additional procedure furnished to the same patient in the same session, as mandated by the Consolidated Appropriations Act of 2015 (enacted December 18, 2015).

Full payment is made for the PC and TC of the highest paid procedure. The TC payment for subsequent procedures will be reduced by 50 percent.

This policy will continue to apply to specified diagnostic imaging services, diagnostic cardiovascular services, diagnostic ophthalmology services, and separately payable "always therapy" services. In the diagnostic cardiovascular services section, 17 nuclear medicine codes are listed as included in the MPPR policy. Cardiology imaging CPT codes 78428–78494 are included on the MPPR list but, at present, no other 78XXX codes.

The MPPR policy is based on CMS's perception that efficiencies exist when furnishing multiple services in the same session due to duplication of physician work—primarily in the pre- and post-service periods, with smaller efficiencies in the intra-service period.

Information Sources:

- A fact sheet summarizing the OPPS and ASC final rule is available at *https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-11-01-3.html*.
- For the list of codes included in the 2017 MPPR policy, go to *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html* and, under Regulations, click on CMS-1654-F. Scroll down to the file name.

FROM VOLUME-BASED TO VALUE-BASED:
Quality Payment Program Ready to Go

The biggest Medicare news in October 2016 related to the release of the MACRA final rule, which implements the new physician quality and value-based payment program and requires eligible clinicians to track the quality of care being delivered to their patients. The Medicare Access & CHIP Reauthorization Act (MACRA) of 2015 mandated that the Department of Health and Human Services (HHS) develop this program to replace the sustainable growth rate (SGR) formula previously used to determine Medicare physician fee schedule payments. In March 2015, Congress repealed the SGR.

According to an announcement from HHS, the new program for clinicians will gradually transform Medicare payments for more than 600,000 clinicians across the country and "accelerate the health care system's shift toward value."

In 2017—the initial implementation phase (also called the transition year), the following are considered eligible clinicians: physicians, osteopaths, dentists, physician assistants, nurse practitioners, clinical nurse specialists, and certified registered nurse anesthetists. In 2019, physical and occupational therapists, speech language pathologists, audiologists, midwives, clinical social workers, psychologists, and dieticians/nutritionists will join the group of eligible clinicians.

Two Participation Tracks

Eligible clinicians may choose one of the tracks summarized below. Together, these make up the new Quality Payment Program (QPP).

Merit-Based Incentive Payment System (MIPS): Clinicians choosing this program will participate in traditional fee-for-service (FFS) Medicare and earn a performance-based payment adjustment. The principal way MIPS measures quality of care is through evidence-based clinical quality measures that MIPS-eligible clinicians can select.

To be eligible for participation, the clinician must bill more than $30,000 to Medicare and provide care to more than 100 Medicare patients per year. What this means is that small practices will not need to report data and will

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not be eligible for a bonus even if they do report.

The Centers for Medicare & Medicaid Services (CMS) will develop and add new clinical practice improvement activities to the QPP and will consolidate components of three existing programs: Physician Quality Reporting System (PQRS), Medicare Electronic Health Record (EHR) Incentive Program for Eligible Professionals, and the Physician Value-Based Payment Modifier. In its summary of the final rule, CMS stated that it would sunset payment adjustments for these programs after January 1, 2018.

Advanced Alternative Payment Model: The second option for participation in the new QPP is the Advanced Alternative Payment Model (APM). Unlike MIPS, this model is not based on Medicare FFS. Instead, participating clinicians receive a Medicare incentive payment based on the quality and cost of care for particular episodes (e.g., bundled payment) or defined patient populations (e.g., accountable care organizations).

Among other requirements, participants in an APM must require participants to use certified EHR technology (CEHRT), and the APM must pay for covered professional services based on quality measures comparable to those in the quality performance category under MIPS.

In an executive summary to the final rule, CMS reported that it is completing an initial set of Advanced APM determinations that it will release as soon as possible but no later than January 1, 2017. All determinations of Advanced APMs will be posted on the CMS website and updated on an ad hoc basis, but no less frequently than annually, as new APMs become available and others end or change.

Reporting Data, Receiving Payment

CMS decided to focus the initial years of the program on encouraging participation and educating clinicians because, it stated in the final rule, "Many eligible clinicians face challenges in understanding the requirements and being prepared to participate...in 2017."

Nonetheless, CMS will use 2017 as the performance period for the 2019 payment adjustment. The first performance period will consist of a minimum of any 90 continuous days in order for clinicians to be eligible for an above-neutral payment adjustment in 2019. In subsequent years, CMS stated that it intends to explore ways to shorten the period between the performance period and the payment year.

Clinicians who are ready may start collecting performance data on January 1, 2017. Those who aren't ready may start anytime between January 1 and October 2, 2017. The end goal, however, is to send in performance data to CMS by March 31, 2018. The data reported (or not reported) in 2017—the transition year—will determine the payment adjustment (positive or negative) received two years later in 2019.

On the new dedicated QPP website, CMS outlines the data-reporting options that clinicians may choose from in addition to the full 90-day period mentioned above. For example, reporting to MIPS for the full year will maximize the clinician's chances to qualify for a positive adjustment. What CMS calls "exceptional performers," as shown by the practice information that they submit, are eligible for an additional positive adjustment for each year of the first six years of the program.

The Hospital Perspective

"Today's final rule presents challenges and opportunities for hospitals and health systems, and the nearly 540,000 directly employed or contracted physicians with whom they partner to deliver quality care," said American Hospital Association (AHA) vice president Tom Nickels in an organizational announcement.

In a previous statement (in response to the proposed rule), the AHA explained:

Hospitals that employ physicians will defray some cost from implementation of and ongoing compliance with the new physician performance reporting requirements, as well as be at risk for any payment adjustments. Moreover, hospitals may participate in advanced APMs to help the physicians with whom they partner qualify for the advanced APM incentives. Finally, as a larger percentage of physician payment becomes at risk, there will likely be a continued shift in hospital-physician relationships, as hospitals and physicians seek greater collaboration on performance measurement and payment models.

While AHA praised CMS for the new payment program, it also has some concerns, such as the narrow definition the agency gave to the advanced APMs (only those listed on the CMS website). Also, the AHA says within the purview of this definition "less than 10% of clinicians will be rewarded for their care transformation efforts."

Information Source: The dedicated web page for the new QPP is *https://qpp.cms.gov/education*.

CMS AWARDS NEW RAC CONTRACTS: Experts Speculate on Future Activity

The Centers for Medicare & Medicaid Services (CMS) have awarded the long-awaited and highly anticipated new round of contracts for the Medicare fee-for-service (FFS) recovery audit contractors (RACs). On October 31, 2016, the agency identified the following as the new RACs:

- Region 1 – Performant Recovery, Inc.
- Region 2 – Cotiviti, LLC (formerly known as Connolly)
- Region 3 – Cotiviti, LLC
- Region 4 – HMS Federal Solutions
- Region 5 – Performant Recovery, Inc.

The RACs in regions 1–4 will perform post-payment review to identify and correct Medicare claims that contain improper payments (overpayments or underpayments) made under Part A and Part B for all provider types other than durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) and home health/hospice. The Region 5 RAC will be dedicated to the post-payment review of DMEPOS and home health/hospice claims nationally.

The statements of work for the new contracts, a map depicting the new regions, and contact information for each RAC are available in the Downloads section of the following website: *https://www.cms.gov/research-statistics-data-and-systems/monitoring-programs/medicare-ffs-compliance-programs/recovery-audit-program/*.

On October 31, CMS also announced that the original Medicare FFS RACs will be under contract until 2018 for administrative purposes. Providers may still receive correspondence related to claims adjusted under the original RAC contracts.

In a November 4, 2016, *RACmonitor* article, Chuck Buck wrote, "For inpatient acute-care hospitals, the new RAC program is not likely to run as wide-open as it did in 2010–2014. CMS is limiting the look-back period for the highly lucrative (from the RACs' perspective) short-stay inpatient claims. CMS is also limiting additional documentation requests (ADRs) across facilities and claim types so that one area of a large health system is not unduly burdened."

For other providers, the story may be much different. Inpatient hospitals received most of the attention between 2010 and 2014 while other areas of the Medicare payment system were ignored. Hospices, for example, were virtually unaudited by RACs despite being an area identified by the U.S.

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Department of Health and Human Services (HHS) Office of Inspector General (OIG) as prone to abuse and possible fraud. Home health agencies have also experienced less auditing relative to inpatient hospitals and will likely be an area of focus under the new RAC contracts.

Backlog of Appeals

Against the backdrop of nearly a million backlogged appeals at the Office of Medicare Hearings and Appeals (OMHA), many in the healthcare industry are concerned about the future RAC audits and the future need for providers to appeal claims denied by the new RACs.

The Medicare appeals process includes statutory deadlines for all five levels of appeal. With regard to the administrative law judge (ALJ) level of review, federal law requires that an ALJ conduct and conclude a hearing and render a decision within 90 days of a request for a hearing. However, as of July 25, 2016, HHS statistics indicated that the average timeframe for the OMHA to process an ALJ appeal was 935 days.

If there is good news in the appointment of the new RACs, it is that the new contractors will be guided by the enhancements announced by CMS in 2015. As stated above, there will be:

- A six-month look-back period for patient status reviews
- A 30-day time limit to complete a review
- A 30-day waiting period to allow time for a discussion prior to forwarding the denial to a Medicare Administrative Contractor (MAC).

Although the CMS announcement is raising many questions within the industry, not knowing when the new contractors will begin requesting records marks a big unknown.

One thing is certain: Audits of coding, medical necessity, DME, and other areas will likely start once CMS gives the go-ahead.

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