CY 2016 Final Rule Summary
Medical Oncology

Medicare Physician Fee Schedule (MPFS)

Provided To:

Revenue Cycle Inc. Client

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Introductory Summary

On October 30, 2015, the Centers for Medicare and Medicaid Services (CMS) issued the final rule for the Medicare Physicians Fee Schedule (MPFS) for CY 2016.

MPFS Final Rule Highlights

The CY 2016 final rule may be located in its entirety by following the link below:
https://s3.amazonaws.com/public-inspection.federalregister.gov/2015-28005.pdf

This document in PDF form is 1358 pages in length. The format of the information on the following pages is intended to summarize information contained within the final rules pertaining to medical oncology services.

CY 2016 MPFS Final Rule Highlights

The highlights and expanded summary of the Final Rule are provided below.

- Conversion Factor = $35.8279 including;
  - Update Factor = 0.5% (1.0005)
  - Budget Neutrality Factor of -0.02% (0.9998)
  - Target Recapture Amount -0.77% (0.9923)
- Estimated Impact on Total Allowed Charges by Specialty:
  - Hematology / Oncology = 0%
- Practice Expense (PE):
  - Comments requesting the inclusion of pharmacists to be included when calculating direct PE costs
  - Indirect costs and utilization of supplemental survey data
- Potentially Misvalued Codes:
  - Potentially misvalued codes identified including 9 codes utilized in medical oncology
  - Based on review of high expenditure services to identify the codes that account for the majority of spending under MPFS
- Evaluation and Management
  - Request for comments regarding the development of add-on codes to represent additional time and effort by practitioners related to evaluation and management services
- Payment for Biosimilar Biological Products:
  - Regulatory text to be amended to clarify the payment amount for biosimilar products is based on the average sales price (ASP) of all National Drug Codes (NDCs) assigned to the biosimilar products included within the same billing and payment code
  - Effective date of January 1, 2016
- Incident to Services:
  - Clarifications regarding appropriate billing physician as the Supervising Physician

- Excluded or revoked auxiliary personnel cannot provide incident to services to Medicare, Medicaid or any other federally funded health care programs
- Telehealth:
  - Finalized additions and rejections of services to the telehealth list
- Physician Value–Based Payment Modifier:
  - Finalized exemption for Pioneer ACO Model, CPC Initiative and similar Innovative Center models including the waiving of requirements for Oncology Care Model (OCM) participants
- Locum Tenens Physicians:
  - Finalized revised definition of locum tenens physician

Conversion Factor & Estimated Impact

The conversion factor (CF) for CY 2016 will be $35.8279. . The CF converts relative value units (RVU) to an actual dollar amount with regards to reimbursement. The value of the CF directly correlates to the pricing of the individual codes reported by physicians and freestanding cancer centers/office settings under the MPFS.

The value of the CF for CY 2016 is slightly lower than the 0.5% increase outlined in the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) released in April 2015. Congress passed legislation in April to remove the Sustainable Growth Rate (SGR) and increase the CF by 0.5% each year, building on the previous year's CF through 2019. CMS must maintain a budget each year and therefore applies a budget neutrality (BN) factor to the CF to help meet the anticipated payments, applying this factor can decrease the overall CF.

For CY 2016, another factor, the Target Recapture Amount, has also been applied to the CF. The Protecting Access to Medicare Act of 2014 (PAMA) included a paragraph in the ACT which requires CMS *"to establish an annual target for reductions in PFS expenditures resulting from adjustments to relative values of misvalued codes."* If the estimated net reduction in expenditures for the year is equal to or greater than the target for the year, then any reduced expenditures attributed to these adjustments will be redistributed in a budget-neutral manner within MPFS and in accordance with the current budget neutrality requirements. If the estimated net reduction in expenditures for the year is less than the target for the year, an amount equal to the target recapture amount will not be taken into account.

Due to several misvalued codes, it was estimated the net reduction in expenditures for CY 2016 would be 0.23%. This does not meet the 1% target established by the Achieving a Better Life Experience Act of 2014 (ABLE), so payments must be reduced by the difference of the target for the year (1%) and the estimated net reduction in expenditures or the Target Recapture Amount (0.23%). This results in a factor of 0.77% reduction to the CY 2016 CF. Table 60 below reflects the factors used to calculate the CF for CY 2016. The CF for CY 2015 is multiplied by the budget neutrality factor, which is then multiplied by the target recapture amount, if applicable, and the answer is the CF value used to determine the reimbursement amount when calculating each CPT/HCPCS code.

TABLE 60: Calculation of the CY 2016 PFS Conversion Factor

Conversion Factor in effect in CY 2015		35.9335
Update Factor	0.5 percent (1.005)	
CY 2016 RVU Budget Neutrality Adjustment	-0.02 percent (0.9998)	
CY 2016 Target Recapture Amount	-0.77 percent (0.9923)	
CY 2016 Conversion Factor		**35.8279**

The following table outlines the combined impact on Hematology and Oncology with regard to RVU changes for CY 2016.

Table 62: CY 2016 PFS Estimated Impact on Total Allowed Charges by Specialty

(A) Specialty	(B) Allowed Charges (mil)	(C) Impact of Work RVU Changes	(D) Impact of PE RVU Changes	(E) Impact of MP RVU Changes	(F) Combined Impact**
Hematology / Oncology	$1,788	0%	0%	0%	0%

The specialties of Radiation Oncology and Gastroenterology will both see the highest negative overall combined impact to reimbursement in CY 2016. These two specialties also had the highest number of CMS created G-codes in CY 2015; which were expected to change over to the AMA CPT codes in CY 2016. CMS stated the following with regard to the decreases experienced by these two specialties. *"Several specialties, including gastroenterology and radiation oncology, will experience significant decreases to payments to services that they frequently furnish as a result of widespread revisions to the structure and the inputs used to develop RVUs for the codes that describe particular services. Other specialties, including pathology and independent laboratories, will experience significant increases to payments for similar reasons."*

Reimbursement

Using the finalized payment information, the following services are provided and payment amounts are based upon the published Medicare allowable for the CPT® codes.

Non-facility rates represent those services provided in a physician office setting and facility rates represent those professional services provided by the physician in a facility setting (hospital outpatient or inpatient). The variance shown in the final two columns illustrate the change in estimated reimbursement as compared to CY 2015.

2015-2016 Medicare Physician Fee Schedule HCPCS Example Impacts

HCPCS Code	Short Descriptor	Non-Facility Payment Rate		Facility Payment Rate		Non-Facility Variance	Facility Variance
		2015 Final	2016 Final	2015 Final	2016 Final		
36415	Routine venipuncture	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
36430	Blood transfusion service	$35.21	$35.11	$35.21	NA	-$0.10	$0.00
36591	Draw blood off venous device	$23.72	$23.65	$23.72	NA	-$0.07	$0.00
36593	Declot vascular device	$31.26	$31.53	$31.26	NA	$0.27	$0.00
38220	Bone marrow aspiration	$167.81	$167.67	$63.60	$63.42	-$0.13	-$0.19
38221	Bone marrow biopsy	$171.04	$170.18	$77.62	$77.03	-$0.86	-$0.59
96360	Hydration iv infusion init	$58.21	$57.68	$58.21	NA	-$0.53	$0.00
96361	Hydrate iv infusion add-on	$15.45	$15.41	$15.45	NA	-$0.05	$0.00
96365	Ther/proph/diag iv inf init	$70.43	$69.86	$70.43	NA	-$0.57	$0.00
96366	Ther/proph/diag iv inf addon	$19.04	$18.99	$19.04	NA	-$0.06	$0.00
96367	Tx/proph/dg addl seq iv inf	$30.54	$30.81	$30.54	NA	$0.27	$0.00
96368	Ther/diag concurrent inf	$20.84	$20.78	$20.84	NA	-$0.06	$0.00
96372	Ther/proph/diag inj sc/im	$25.51	$25.44	$25.51	NA	-$0.07	$0.00
96374	Ther/proph/diag inj iv push	$57.49	$57.32	$57.49	NA	-$0.17	$0.00
96375	Tx/pro/dx inj new drug addon	$22.64	$22.57	$22.64	NA	-$0.07	$0.00
96376	Tx/pro/dx inj same drug adon	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
96401	Chemo anti-neopl sq/im	$75.46	$75.24	$75.46	NA	-$0.22	$0.00
96402	Chemo hormon antineopl sq/im	$32.70	$32.60	$32.70	NA	-$0.10	$0.00
96409	Chemo iv push sngl drug	$111.75	$111.42	$111.75	NA	-$0.33	$0.00
96411	Chemo iv push addl drug	$62.52	$62.70	$62.52	NA	$0.17	$0.00
96413	Chemo iv infusion 1 hr	$136.55	$136.15	$136.55	NA	-$0.40	$0.00
96415	Chemo iv infusion addl hr	$28.39	$28.66	$28.39	NA	$0.27	$0.00
96416	Chemo prolong infuse w/pump	$141.58	$141.52	$141.58	NA	-$0.06	$0.00
96417	Chemo iv infus each addl seq	$63.24	$63.06	$63.24	NA	-$0.19	$0.00
96450	Chemotherapy into cns	$184.34	$183.80	$82.29	$82.40	-$0.54	$0.12
96521	Refill/maint portable pump	$139.42	$138.65	$139.42	NA	-$0.77	$0.00
96523	Irrig drug delivery device	$25.15	$25.08	$25.15	NA	-$0.07	$0.00
99195	Phlebotomy	$101.69	$100.68	$101.69	NA	-$1.02	$0.00
G0364	Bone marrow aspirate &biopsy	$12.58	$12.54	$8.98	$8.96	-$0.04	-$0.03
99201	Office/outpatient visit new	$44.20	$44.43	$26.95	$27.23	$0.23	$0.28
99202	Office/outpatient visit new	$75.46	$75.60	$50.67	$50.88	$0.14	$0.21
99203	Office/outpatient visit new	$109.60	$109.28	$77.98	$77.75	-$0.32	-$0.23

99204	Office/outpatient visit new	$166.73	$166.24	$131.88	$131.49	-$0.49	-$0.39
99205	Office/outpatient visit new	$209.49	$208.52	$171.40	$170.90	-$0.97	-$0.50
99211	Office/outpatient visit est	$20.12	$20.06	$9.34	$9.32	-$0.06	-$0.03
99212	Office/outpatient visit est	$44.20	$44.07	$25.87	$25.80	-$0.13	-$0.08
99213	Office/outpatient visit est	$73.30	$73.45	$51.38	$51.59	$0.14	$0.21
99214	Office/outpatient visit est	$108.88	$108.20	$79.41	$79.18	-$0.68	-$0.23
99215	Office/outpatient visit est	$146.97	$145.82	$112.83	$111.78	-$1.15	-$1.05

Practice Expense (PE)

Practice Expense Relative Value Units (PE RVU) are a component of the MPFS reimbursement equation and are assigned on a per CPT® code basis. The components of the PE methodology that are assessed when valuing the associated codes for reimbursement are expenses including direct and indirect costs.

Comments received regarding the CY 2016 Proposed Rules requested that CMS include pharmacists as active qualified health care providers for purposes of calculating physician PE direct costs. The commenters also referenced the pharmacist's role in contributions related to redesigning healthcare delivery and financing and the absence of these pharmacists would result in a negative impact on the health care system. In response to the commenters, CMS requested stakeholders to provide more detailed information regarding pharmacists' typical labor costs for specific services described by HCPCS codes for which payment is made under MPFS.

For the indirect costs, CMS will continue to utilize supplemental survey data to reflect the Practice Expense per Hour Data for oncology drug administration services utilized by medical oncology, hematology and hematology/oncology.

Potentially Misvalued Codes

The general public and stakeholders can submit requests to review potentially misvalued codes. Codes nominated during the 60-day comment period to the final rule release are evaluated to determine if the information provided reveals codes, which may be misvalued. In the following year's MPFS proposed rules the list of nominated codes will be released for comment.

Another way in which potentially misvalued codes are nominated for review is through the high expenditure screening tool. This tool screens for codes, which account for the majority of spending under MPFS. For CY 2016, 118 codes were proposed as potentially misvalued, which were identified per the high expenditure screening tool; however, codes reviewed since 2010, those with fewer than $10 million in allowed charges and any anesthesia or E&M services were excluded. The codes selected do not mean they are misvalued, but due to the selection criteria or documentation provided, they *may* be misvalued. Additionally, when the RUC submits recommendations to CMS about a particular code, CMS will remove

that code from the potentially misvalued list regardless of how the RUC reviewed the code and even if it was not reviewed through a particular screening process.

The table below reflects services utilized in hematology/oncology and are components of procedures performed on cancer patients.

TABLE 8: List of Potentially Misvalued Codes Identified Through High Expenditure by Specialty Screen

HCPCS	Short Descriptor
38221	Bone marrow biopsy
96360	Hydration iv infusion init
96372	Ther/proph/diag inj sc/im
96374	Ther/proph/diag inj iv push
96375	Tx/pro/dx inj new drug addon
96401	Chemo anti-neopl sq/im
96402	Chemo hormon antineopl sq/im
96409	Chemo iv push sngl drug
96411	Chemo iv push addl drug

Evaluation and Management Services

Within the final rule, CMS made comment to the receipt of requests from stakeholders to review the current E&M codes or construct a new set of codes. These new codes would provide a better way to describe and value the work specific to primary care and other cognitive specialties in context to complex patient care. The stakeholders have suggested the current E&M services do not account for the additional time spent treating acute illnesses and time spent working toward optimal outcomes for patients with critical conditions or those treated episodically. The current E&Ms are utilized to describe work of a wide range of practitioners; however, the stakeholders explain additional work is required of some practitioners. Examples provided included, medication reconciliation, the assessment and integration of numerous data points, effective coordination of care among multiple other clinicians, collaboration with team members, continuous development and modification of care plans, patient or caregiver education, and the communication of test results.

As a result of these comments, CMS has requested public comments on ways to recognize the different resources involved in delivering broad-based, ongoing treatment, beyond those resources already incorporated in the current E&M codes. CMS indicated the interest is in determining codes to be used in addition to, rather than instead of, the current E&M codes. CMS felt these codes may be similar to the existing add-on codes currently in use and may allow for reporting of additional time and intensity required of primary care and cognitive specialties in conjunction with E&M services. CMS encouraged stakeholders

to comment on this issue in order to assist in developing proposals to be published in future CY 2016 rulemaking for potential implementation in CY 2017.

Payment for Biosimilar Biological Products

Under the Affordable Care Act, a reduced pathway for licensing for biosimilar biological products was established, which allows a proposed biological product that is demonstrated to be biosimilar to a reference product can rely on certain existing scientific knowledge about the safety, purity, and potency of the reference product to support licensure. The Act also defined the payment methodology for these products and CMS published regulations for the payment for biosimilar biological products administered in a physician's office in the CY 2011 Medicare Physicians Fee Schedule final rule. Section 3139 of the Affordable Care Act amended section 1847A of the Act to define a biosimilar biological product and a reference biological product, and to provide for Medicare payment of biosimilar biological products using the average sale price (ASP) methodology.

Section 1847A(b) of the Affordable Care Act was also amended by adding a new paragraph to specify the payment amount for a biosimilar biological product will be the sum of the ASP, as determined using the methodology described under paragraph 1847A(b)(6), applied to a biosimilar biological product for all National Drug Codes (NDCs) assigned to such product in the same manner; and 6% of the payment amount determined using the methodology in section 1847A(b)(4) of the Act for the corresponding reference biological product. The effective date for ASP statutory provisions on biosimilars was July 1, 2010. At that time, it was unclear as to how and when the new Food and Drug Administration (FDA) approval pathway would be implemented or when biosimilar products would be approved.

On March 6, 2015, the first FDA approved biosimilar product was approved and CMS expects additional products to be approved. As the biosimilars are emerging, CMS has reviewed the existing guidance on payment and realized potential inconsistencies between the interpretation of the statutory language at section 1847A(b)(8) of the Act and regulation text at §414.904(j). Within the proposed rule, CMS identified changes to guidance and clarification where needed. Comments received pertinent to the proposed changes were received from individuals, pharmaceutical manufacturers, patient advocate groups, providers and members of the House of Representatives. Many of the commenters requested a different payment amount for each biosimilar product and recommendations were made to be mindful of the policy as the marketplace evolves.

Per the final rule, CMS has finalized the proposal to amend the regulation text at §414.904(j) to specify the payment amount for a biosimilar biological product will be based on the ASP of all NDCs assigned to the biosimilar biological products included within the same billing and payment code. The effective date will be January 1, 2016. CMS indicated due to the degree of similarity that biosimilars share with their reference products, they felt it is appropriate to price these items in groups similar to how multiple source or generic drugs are priced. CMS stated they believe the biosimilar payment policy should mirror that for multiple

source drugs; therefore, CMS will have the discretion to calculate the ASP-based payment for grouped biosimilars in the same manner as the methodology used for grouped multiple source drugs.

Commenters expressed concern over the appropriate clinical use of the drugs and medical recordkeeping issues that may result; however, CMS defined these concerns are outside of the scope of the final rule. CMS did however indicate they were not aware of provider confusion resulting from the drug groupings and provided an example of the HCPCS J3489, which includes drugs such as Reclast®, Zometa® and generic versions of both zoledronic acid products.

CMS also outlined how payments for newly approved biosimilars will be determined, which involves the receipt of manufacturers' ASP sales data through the ASP data submission process and publication of national payment amounts consistent with pricing for other drugs and biologicals. CMS anticipates the biosimilar products will have a lower ASP than corresponding reference products, which will provide savings for the Medicare Program. At the writing of the rule, CMS had not received ASP data for any biosimilars approved under the FDA's biosimilar approval pathway and CMS is unaware of how many biosimilar products will be approved; however, CMS expects some degree of savings will be realized.

Incident-to Services

CMS proposed changes for incident to in light of questions received from providers as to the appropriate physician to report services under on the claim form. In response to commenters seeking clarification regarding which physician to bill under for an incident to service, CMS is adjusting and updating the guidelines related to incident to services.

Incident to services require direct supervision of the auxiliary personnel providing the service by the physician or other practitioner. CMS is adjusting language to define the physician who supervises the service(s) is the billing physician. CMS stated, *"To be certain that the incident to services furnished to a beneficiary are in fact an integral, although incidental, part of the physician's or other practitioner's personal professional service that is billed to Medicare, we believe that the physician or other practitioner who bills for the incident to service must also be the physician or other practitioner who directly supervises the service. It has been our position that billing practitioners should have a personal role in, and responsibility for, furnishing services for which they are billing and receiving payment as an incident to their own professional services."* This statement coincides with the attestation statement on the back of the CMS1500 claim form submitted by the physician for payment of services. The attestation statement indicates the physician listed on the Medicare claim "personally furnished" the services reported on the particular claim form.

CMS is also revising the last sentence of the policy to state *"that the physician (or other practitioner) supervising the auxiliary personnel need not be the same physician (or other practitioner) treating the patient more broadly."* CMS is also adding clarifying text, *"that only the physician or other practitioner*

under whose supervision the incident to service(s) are being provided is permitted to bill the Medicare program for the incident to services."

CMS is also finalizing the changes in regulation regarding the auxiliary personnel permitted to provide incident to services under the direction of a physician. These regulations will not allow any individuals who have been excluded from the Medicare program or have had Medicare enrollment revoked to perform services incident to the physician.

Telehealth

CMS finalized six CPT® codes to be added to the telehealth list for CY 2016. Requests to add services to the list of Medicare telehealth services must be submitted and received no later than December 31 of each calendar year to be considered for the next rulemaking cycle.

CMS received requests in CY 2014 for services effective for CY 2016. Upon review of these services, Medicare found the services were similar to procedures and visits currently on the telehealth list; therefore, would qualify to be added to the list for CY 2016. The additions include:

- 99356 (prolonged service in the inpatient or observation setting, requiring unit/floor time beyond the usual service; first hour (list separately in addition to code for inpatient evaluation and management service);
- 99357 (prolonged service in the inpatient or observation setting, requiring unit/floor time beyond the usual service; each additional 30 minutes (list separately in addition to code for prolonged service);
- 90963 (end-stage renal disease (ESRD) related services for home dialysis per full month, for patients younger than 2 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents);
- 90964 (end-stage renal disease (ESRD) related services for home dialysis per full month, for patients 2-11 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents);
- 90965 (end-stage renal disease (ESRD) related services for home dialysis per full month, for patients 12-19 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents)
- 90966 (end-stage renal disease (ESRD) related services for home dialysis per full month, for patients 20 years of age and older)

CMS also received requests to add services, which did not meet the criteria for telehealth services, including all evaluation and management services, telerehabilitation services, palliative care, pain management and patient navigation services for cancer patients. CMS indicated the decision was made based on the lack of specific codes that were being requested for review and two of the requests did not include evidence of clinical benefit when furnished via telehealth.

Critical care codes 99291 (critical care, evaluation and management of the critically ill or critically injured patient; first 30-74 minutes); and 99292 (critical care, evaluation and management of the critically ill or critically injured patient; each additional 30 minutes (list separately in addition to code for primary service) were also requested to be added. Per CMS, they did not accept this request as there was no evidence suggesting that the use of telehealth could be a reasonable surrogate for the face-to-face delivery of this type of care.

CMS also indicated that services that are not separately payable by Medicare would not be appropriate to be included as a telehealth service. As a result, CMS did not propose or finalize the addition of any nonpayable services to the Medicare telehealth services list for CY 2016. For the complete list of covered telehealth services, see the CMS website at www.cms.gov/teleheath/

Physician Value–Based Payment Modifier

Section 1848(p) of the Affordable Care Act required CMS to develop a value-based payment modifier (VM) and apply it to specific physicians and groups of physicians the Secretary determines appropriate starting January 1, 2015, and to all physicians and groups of physicians by January 1, 2017. The VM program includes quality and cost measures to help determine payment adjustments and an indication of whether an individual provider or group is meeting the Affordable Care Act goals of improving quality and lowering costs.

Rulemaking in previous years finalized policies to apply the VM program beginning in January 1, 2015 for physicians in groups of 100 or more, January 1, 2016 for physicians in groups of 10 or more and January 1, 2017 for physicians in groups of 2 or more and physician solo practitioners. Starting January 1, 2018, VM will apply to nonphysician practitioners in groups with 2 or more eligible providers or solo practitioners.

As part of this proposed rule, CMS outlined various VM policy changes with the final rule. One of these proposed changes pertained to the exemption of practitioners and groups participating in similar programs, such as the Pioneer ACO Model and CPC Initiative. Previous rulemaking also finalized criteria to be used to determine if future Innovation Center models or CMS initiatives are similar to the Pioneer ACP Model and CPC Initiative and the same VM policies would be adopted for similar models.

The Oncology Care Model (OCM) is one of these Innovation Center models starting in 2016. OCM is an episode-based model that provides an incentive for participating practices to reduce the total cost of care for 6-month episodes triggered by either an initial chemotherapy administration claim or initial Part D chemotherapy claim. This model utilizes a set of measures specific to oncology and will use a quarterly reporting period that is different than the calendar year performance period for the VM. Due to the specialty-specific measure set and alternative reporting period, CMS has finalized waiving the VM for these practices in order to minimize conflicting incentives between programs with regard to the evaluation of quality of cost and care.

Locum Tenens

CMS sought comment on updating the definition of Locum Tenens; however, no comments were received. Therefore, CMS finalized revision of definition of locum tenens physician to remove the reference to "stand in the shoes." CMS believes the definition of locum tenens is clear without it.

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