

**Overview of Selected Provisions of the Hospital Outpatient Prospective  
Payment System and Ambulatory Surgical Center Payment System  
Proposed Rule for Calendar Year 2018**

On July 13, 2017, the Centers for Medicare & Medicaid Services (CMS) released the hospital outpatient prospective payment system (OPPS) and ambulatory surgical center (ASC) payment system proposed rule for the calendar year (CY) 2018 (the “Proposed Rule”). The Proposed Rule was published in the Federal Register on July 20, 2017,<sup>1</sup> and CMS will accept comments on it until September 11, 2017.

CMS proposes to increase payment rates under the OPPS by 1.75 percent. This reflects a 2.9 percent increase in the hospital inpatient market basket, a -0.4 percent multifactor productivity adjustment, and a 0.75 percent reduction required by the Affordable Care Act (ACA). Hospitals that fail to meet the hospital outpatient quality reporting requirements will receive an update that is reduced by 2.0 percent. CMS expects that total Medicare payments to OPPS providers would be approximately \$70 billion, an increase of approximately \$5.7 billion compared to CY 2017.<sup>2</sup> Medicare payments to ASCs would be approximately \$4.68 billion, an increase of \$155 million from CY 2017.<sup>3</sup>

The addenda containing relative weights, payment rates, wage indices, and other payment information are available only on the CMS web site. Addenda relating to the OPPS are available at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices-Items/CMS-1678-P.html>. Addenda relating to the ASC payment system are available at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Regulations-and-Notices-Items/CMS-1678-P.html>.

**This Summary Addresses the Following Topics in the CY 2018 Proposed Rule:**

- (1) Packaging policies:
  - a. Packaging threshold for drugs, biologicals, and radiopharmaceuticals
  - b. Packaging high/low cost threshold for packaged skin substitutes
  - c. Single packaging determination for Healthcare Common Procedure Coding System (HCPCS) codes that describe the same drug or biological but in different doses
- (2) Comprehensive Ambulatory Payment Classifications (C-APCs)
- (3) Revision of New Technology Ambulatory Payment Classifications (APCs)
- (4) Drugs, biologicals, and devices with expiring pass-through payment status in CY 2017 or with new or continuing pass-through status in CY 2018
  - a. Drugs and biologicals
  - b. Devices

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<sup>1</sup> 82 Fed. Reg. 33,558 (Jul. 20, 2017).

<sup>2</sup> *Id.* at 33,564.

<sup>3</sup> *Id.* at 33,565.

- (5) Alternative payment methodology for drugs purchased under the 340B drug discount program
- (6) Proposals regarding drug administration services
  - a. Proposed packaging of Level 1 and Level 2 drug administration services
  - b. Proposed payment rates for drug administration services
- (7) Payment for radiation oncology services
- (8) Proposed treatment of new and revised CY 2018 category I and III Current Procedural Terminology (CPT®)<sup>4</sup> codes
- (9) Proposed treatment of new CY 2018 Level II HCPCS and Category III CPT codes
- (10) Care management coding changes effective January 1, 2018
- (11) Proposed changes to APCs
  - a. Creation of a new imaging APC
  - b. Proposed APC exceptions to the 2 times rule
- (12) Changes to procedures that would be paid only as inpatient procedures
- (13) Payment adjustments
  - a. Cancer hospital payment adjustments
  - b. Payment changes for film x-ray and computed radiography technology
  - c. Potential revisions to laboratory date of service policies
- (14) Proposals regarding device-intensive procedures
  - a. Proposal for HCPCS level device-intensive status and device edits
  - b. OPPS payment adjustment for no cost/partial credit devices
  - c. Proposed payment policy for low-volume intensive procedures
- (15) Payment for certain items and services furnished by certain off-campus provider based departments
- (16) Enforcement Instruction for the Supervision of Outpatient Therapeutic Services in Critical Access Hospitals (CAHs) and Certain Small Rural Hospitals
- (17) Hospital Outpatient Quality Reporting (OQR) Program
  - a. Addition, Removal, or Delay of Quality Measures from the Hospital OQR Program Measure Set
  - b. Future Measure Topics
  - c. Possible Future Adoption of the Electronic Version of OP-2: Fibrinolytic Therapy Received Within 30 Minutes of Emergency Department Arrival
  - d. Public Display of Quality Measures
  - e. Administrative Requirements
  - f. Form, Manner, and Timing of Data Submitted for the Hospital OQR Program
  - g. Hospital OQR Program Validation Requirements for Chart-Abstracted Measure Data Submitted Directly to CMS for the CY 2020 Payment Determination and Subsequent Years
  - h. Proposed Formalization and Modifications to the Educational Review Process for Chart-Abstracted Measures Validation
  - i. Extraordinary Circumstances Exception Process for the CY 2020 Payment Determination and Subsequent Years
- (18) ASC Quality Reporting (ASCQR) Program
  - a. New, Removed or Delayed Quality Measures from the ASCQR Measure Set
  - b. Future Measure Topics
  - c. Form, Manner, and Timing of Data Submitted for the ASCQR Program

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<sup>4</sup> CPT is a trademark of the American Medical Association (AMA).

- d. Extraordinary Circumstances Exception Process for the CY 2020 Payment Determination and Subsequent Years
- (19) Medicare site-of-service price transparency
  - (20) Request for information and public comments

**CMS Has *Not* Proposed Changes to the Following Policies:**

- (a) Payment for biosimilar biological products. The payment rate would continue to be 100 percent of the biosimilar's ASP plus six percent of the reference product's average sales price (ASP) when the product has pass-through status. The same rate would apply to nonpass-through biosimilar biological products with costs that exceed the packaging threshold.<sup>5</sup>
- (b) Payment for drugs and biologicals with pass-through status, including policy-packaged drugs (contrast agents, diagnostic radiopharmaceuticals, anesthesia drugs; drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure and drugs; and biologicals that function as supplies when used in a surgical procedure), and diagnostic and therapeutic radiopharmaceuticals. Payment would remain at ASP plus six percent.<sup>6</sup>
- (c) Payment for blood clotting factors. Payment would continue to be made at ASP plus six percent and a furnishing fee using an updated amount would continue to be provided.<sup>7</sup>
- (d) Payment for blood and blood products. Payment rates for blood and blood products would continue to be established using the agency's blood-specific cost-to-charge ratio (CCR) methodology. Because the costs of blood and blood products are reflected in the overall costs of C-APCs, CMS would continue to not make separate payments for blood and blood products when they appear on the same claims as services assigned to C-APCs.<sup>8</sup>
- (e) Payment for brachytherapy sources. Payment rates would continue to be set for brachytherapy sources using CMS's established prospective payment methodology, based on geometric mean costs for each source.<sup>9</sup>
- (f) Outlier payments. CMS would continue to estimate outlier payments to be one percent of the aggregate total payments under the OPPS.<sup>10</sup>
- (g) Payment adjustment policy for radioisotopes derived from non-highly enriched uranium (non-HEU) sources. An additional payment of \$10 would continue to be provided for radioisotopes produced by non-HEU sources.<sup>11</sup>
- (h) Process for new Level II HCPCS codes that will be effective October 1, 2017 and January 1, 2018. CMS proposes to continue its established policy of assigning comment indicator "NI" in Addendum B to the OPPS final rule to those new Level II HCPCS codes that are effective October 1 and January 1 to indicate that CMS is assigning them an interim payment status that is subject to public comment.<sup>12</sup>

**Details about the proposed changes are provided below.**

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<sup>5</sup> 82 Fed. Reg. at 33,630.

<sup>6</sup> *Id.* at 33,622.

<sup>7</sup> *Id.* at 33,631.

<sup>8</sup> *Id.* at 33,571-572.

<sup>9</sup> *Id.* at 33,572.

<sup>10</sup> *Id.* at 33,597.

<sup>11</sup> *Id.* at 33,631.

<sup>12</sup> *Id.* at 33,603.

(1) Packaging Policies

a. *Packaging threshold for drugs, biologicals, and radiopharmaceuticals*

CMS proposes to update the packaging threshold for drugs and biologicals from \$110 to \$120. CMS proposes to package drugs and biologicals with a per-day cost less than or equal to \$120 and pay separately for drugs and biologicals with a per day cost greater than \$120.<sup>13</sup>

b. *Packaging high/low cost threshold for packaged skin substitutes*

With regard to the packaging of skin substitutes, CMS's current policy is to divide skin substitutes into a "high cost group" and a "low cost group" to ensure adequate resource homogeneity among APC assignments for the skin substitute application procedures.<sup>14</sup> CMS is proposing to assign each skin substitute to one of these groups based on whether its mean unit cost (MUC) or per day cost (PDC) exceeds either the MUC threshold of \$47/cm<sup>2</sup> or the PDC threshold of \$755. The agency notes that some skin substitute manufacturers have raised concerns about significant fluctuation in the MUC threshold and the PDC threshold from year to year. Because of these concerns, CMS proposes to continue to assign products that are in the high cost group in 2017 to the high cost group in 2018, regardless of whether they exceed the CY 2018 MUC or PDC threshold.<sup>15</sup> CMS says it wants to "maintain similar levels of payment" while it studies its methodology to determine if refinements are needed.<sup>16</sup>

The following products do not exceed either the MUC or PDC threshold for CY 2018, but are proposed to be assigned to the high cost group because they were assigned to the high cost group in CY 2017<sup>17</sup>:

<b>CY 2018 HCPCS Code</b>	<b>CY 2018 Short Descriptor</b>
Q4103	Oasis Burn Matrix
Q4110	Primatrix
Q4122	Dermacell
Q4127	Talymed
Q4147	Architect ecm, 1 cm
Q4158	MariGen 1 Square cm
Q4161	Bio-Connekt per square cm

c. *Single packaging determination for HCPCS codes that describe the same drug or biological but in different doses*

CMS proposes to continue to make packaging determinations for HCPCS codes that describe the same drug or biological but are in different doses on a drug-specific basis (as

<sup>13</sup> *Id.* at 33,625.

<sup>14</sup> *Id.* at 33,626.

<sup>15</sup> *Id.*

<sup>16</sup> *Id.*

<sup>17</sup> *Id.* at 33,628.

opposed to a HCPCS code basis) to avoid creating financial incentives to pick one HCPCS code over the other.<sup>18</sup> Table 25 in the Proposed Rule provides a list of the HCPCS codes to which the CY 2018 drug-specific packaging determination methodology applies.<sup>19</sup>

(2) Comprehensive Ambulatory Payment Classifications (C-APCs)

For CY 2018, CMS proposes to continue to implement the C-APC payment methodology made effective in CY 2015. CMS does not propose to create any new C-APCs for CY 2018.<sup>20</sup>

CMS proposed to make a few relatively minor changes to the C-APC payment methodology, including, but not limited to:

- Establishing a code edit that requires a brachytherapy treatment code when a brachytherapy insertion code is billed.<sup>21</sup>
- Deleting the “CP” modifier (currently used to identify adjunctive services reported on separate claims) and discontinuing its required use for stereotactic radiosurgery (SRS), C-APC 5627 (Level 7 Radiation Therapy), HCPCS codes 77371 and 77372.<sup>22</sup>
- Proposing to create a new HCPCS C-code to describe blue light cystoscopy (HCPCS code C97XX (Adjunctive blue light cystoscopy with fluorescent imaging agent (List separately in addition to code for primary procedure)) and to allow for a complexity adjustment to APC 5374 (Level 4 Urology and Related Services) when a white light followed by blue light cystoscopy procedure is performed.<sup>23</sup>

(3) Revision of New Technology APCs

CMS proposes to narrow the cost bands of certain New Technology APC groups and to add one additional pair of New Technology APCs. The new pair will have a payment level, ranging from \$145,001-\$160,000, with one set subject to the multiple procedure payment reduction (status indicator T) and the other set not subject to the multiple procedure payment reduction (status indicator S).<sup>24</sup> CMS also proposes to narrow the cost bands of New Technology APCs 1901 through 1906 from \$19,999 cost bands to \$14,999 cost bands.<sup>25</sup> Table 17 in the Proposed Rule summarizes the changes to the New Technology APCs and is reproduced below.<sup>26</sup>

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<sup>18</sup> *Id.*

<sup>19</sup> *Id.* at 33,629.

<sup>20</sup> *Id.* at 33,576.

<sup>21</sup> *Id.* at 33,577.

<sup>22</sup> *Id.* at 33,578-579.

<sup>23</sup> *Id.* at 33,579-580.

<sup>24</sup> *Id.* at 33,606.

<sup>25</sup> *Id.*

<sup>26</sup> *Id.*

<b>CY 2018 Proposed APC</b>	<b>Proposed CY 2018 APC Title</b>	<b>Proposed CY 2018 SI</b>	<b>Type of Change</b>
1901	New Technology - Level 49 (\$100,001-\$115,000)	S	Updated APC
1902	New Technology - Level 49 (\$100,001-\$115,000)	T	Updated APC
1903	New Technology - Level 50 (\$115,001-\$130,000)	S	Updated APC
1904	New Technology - Level 50 (\$115,001-\$130,000)	T	Updated APC
1905	New Technology - Level 51 (\$130,001-\$145,000)	S	Updated APC
1906	New Technology - Level 51 (\$130,001-\$145,000)	T	Updated APC
1907	New Technology - Level 52 (\$145,001-\$160,000)	S	New APC
1908	New Technology - Level 52 (\$145,001-\$160,000)	T	New APC

(4) *Drugs, biologicals, and devices with expiring pass-through payment status in CY 2017 or with new or continuing pass-through status in CY 2018*

CMS estimates total pass-through spending for the devices, drugs, and biologicals receiving pass-through payment in CY 2018 to be approximately \$26.2 million.<sup>27</sup> This projected spending is less than 2.0 percent of total program payments and therefore will not trigger a uniform prospective reduction. The estimate includes \$10 million for device categories that are anticipated to become newly eligible for pass-through payment in CY 2018, \$7.7 million for known drugs and biologicals eligible for pass-through payment, and \$8.5 million for drugs and biologicals that are anticipated to become newly eligible for pass-through payment in CY 2018. There are no device categories currently eligible for pass-through payment in CY 2018.

a. *Drugs and biologicals*

CMS proposes to reimburse drugs with pass-through status at ASP plus six percent. CMS proposes that the pass-through status of the 19 drugs and biologicals listed below would expire on December 31, 2017.<sup>28</sup>

<sup>27</sup> *Id.* at 33,637.

<sup>28</sup> *Id.* at 33,621-22.

<b>CY 2017 HCPCS CODE</b>	<b>CY 2017 LONG DESCRIPTOR</b>	<b>CY 2017 STATUS INDICATOR</b>	<b>CY 2017 APC</b>
<b>A9586</b>	Florbetapir fl 8, diagnostic, per study dos, up to 10 millicuries	G	1664
<b>C9447</b>	Injection, phenylephrine and ketorolac, 4 ml vial	G	1663
<b>J0596</b>	Injection, c-1 esterase inhibitor (human), Ruconest, 10 units	G	9445
<b>J0695</b>	Injection, ceftolozane 50 mg and tazobactam 25 mg	G	9452
<b>J0875</b>	Injection, dalbavancin, 5 mg	G	1823
<b>J1833</b>	Injection, isavuconazonium sulfate, 1 mg	G	9456
<b>J2407</b>	Injection, oritavancin, 10 mg	G	1660
<b>J2502</b>	Injection, pasireotide long acting, 1 mg	G	9454
<b>J2547</b>	Injection, peramivir, 1 mg	G	9451
<b>J2860</b>	Injection, siltuximab, 10 mg	G	9455
<b>J3090</b>	Injection, tedizolid phosphate, 1 mg	G	1662
<b>J7313</b>	Injection, fluocinolone acetonide intravitreal implant, 0.01 mg	G	9450
<b>J8655</b>	Netupitant (300 mg) and palonosetron (0.5 mg)0	G	9448
<b>J9032</b>	Injection, belinostat, 10 mg	G	1658
<b>J9039</b>	Injection, blinatumomab, 1 mcg	G	9449
<b>J9271</b>	Injection, pembrolizumab, 1 mg	G	1490
<b>J9299</b>	Injection, nivolumab, 1 mg	G	9453
<b>Q4172</b>	PuraPly, and PuraPly Antimicrobial, any type, per square centimeter	G	1657
<b>Q9950</b>	Injection, sulfur hexafluoride lipid microsphere, per ml	G	9457

CMS will continue pass-through payments for CY 2018 for the 38 drugs and biologicals listed below.<sup>29</sup>

<b>CY 2018 HCPCS CODE</b>	<b>CY 2018 LONG DESCRIPTOR</b>	<b>CY 2018 STATUS INDICATOR</b>	<b>CY 2018 APC</b>
<b>A9515</b>	Choline C 11, diagnostic, per study dose	G	9461
<b>A9587</b>	Gallium ga-68, dotatate, diagnostic, 0.1 millicurie	G	9056
<b>A9588</b>	Fluciclovine f-18, diagnostic, 1 millicurie	G	9052
<b>C9140</b>	Injection, Factor VIII (antihemophilic factor, recombinant) (Afstyl), 1 I.U.	G	9043
<b>C9460</b>	Injection, cangrelor, 1 mg	G	9460
<b>C9482</b>	Injection, sotalol hydrochloride, 1 mg	G	9482
<b>C9483</b>	Injection, atezolizumab, 10 mg	G	9483
<b>C9484</b>	Injection, eteplirsen, 10 mg	G	9484
<b>C9485</b>	Injection, olaratumab, 10 mg	G	9485
<b>C9486</b>	Injection, granisetron extended release, 0.1 mg	G	9486
<b>Q9989</b>	Ustekinumab, for Intravenous Injection, 1 mg	G	9487
<b>C9488</b>	Injection, conivaptan hydrochloride, 1 mg	G	9488

<sup>29</sup> *Id.* at 33,622-23.

<b>C9489</b>	Injection, nusinersen, 0.1 mg	G	9489
<b>C9490</b>	Injection, bezlotoxumab, 10 mg	G	9490
<b>J0570</b>	Buprenorphine implant, 74.2 mg	G	9058
<b>J1942</b>	Injection, aripiprazole lauroxil, 1 mg	G	9470
<b>J2182</b>	Injection, mepolizumab, 1 mg	G	9473
<b>J2786</b>	Injection, reslizumab, 1 mg	G	9481
<b>J2840</b>	Injection, sebelipase alfa, 1 mg	G	9478
<b>J7179</b>	Injection, von willebrand factor (recombinant), (vonvendi), 1 i.u. vwf:rho	G	9059
<b>J7202</b>	Injection, Factor IX, albumin fusion protein (recombinant), Idelvion, 1 i.u.	G	9171
<b>J7207</b>	Injection, Factor VIII (antihemophilic factor, recombinant) PEGylated, 1 I.U.	G	1844
<b>J7209</b>	Injection, Factor VIII (antihemophilic factor, recombinant) (Nuwiq), per i.u.	G	1846
<b>J7322</b>	Hyaluronan or derivative, Hymovis, for intra-articular injection, 1 mg	G	9471
<b>J7328</b>	Hyaluronan or derivative, gel-syn, for intra-articular injection, 0.1 mg	G	1862
<b>J7342</b>	Instillation, ciprofloxacin otic suspension, 6 mg	G	9479
<b>J7503</b>	Tacrolimus, extended release, (envarsus xr), oral, 0.25 mg	G	1845
<b>J9034</b>	Injection, bendamustine hcl (Bendeka), 1 mg	G	1861
<b>J9145</b>	Injection, daratumumab, 10 mg	G	9476
<b>J9176</b>	Injection, elotuzumab, 1 mg	G	9477
<b>J9205</b>	Injection, irinotecan liposome, 1 mg	G	9474
<b>J9295</b>	Injection, necitumumab, 1 mg	G	9475
<b>J9325</b>	Injection, talimogene laherparepvec, 1 million plaque forming units (PFU)	G	9472
<b>J9352</b>	Injection, trabectedin, 0.1 mg	G	9480
<b>Q5101</b>	Injection, Filgrastim (G-CSF), Biosimilar, 1 microgram	G	1822
<b>Q5102</b>	Injection, Infliximab, Biosimilar, 10 mg	G	1847
<b>Q9982</b>	Flutemetamol F18, diagnostic, per study dose, up to 5 millicuries	G	9459
<b>Q9983</b>	Florbetaben F18, diagnostic, per study does, up to 8.1 millicuries	G	9458

*b. Devices*

CMS proposes that the pass-through payment status for following three categories of devices will expire on December 31, 2017:

<b>Expired HCPCS Code</b>	<b>Description</b>
C2623	Catheter, transluminal angioplasty, drug-coated, non-laser
C2613	Lung biopsy plug with delivery system
C1822	Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system



The pass-through payment status for these device categories began on April 1, 2015, July 1, 2015, and January 1, 2016 respectively.<sup>30</sup>

CMS also discusses five devices whose applications for pass-through status were not approved during the quarterly review process:

- Architect PX
- Dermavest and Plurivest Human Placental Connective Tissue Matrix
- FloGraft and FloGraft Neogenesis
- Kerecis Omega 3 Wound
- X-Wrap

CMS seeks comments on whether these devices meet the criteria for pass-through status.<sup>31</sup>

(5) Payment for separately payable drugs and alternative payment methodology for drugs purchased under the 340B drug discount program

CMS proposes to continue to pay for most specified covered outpatient drugs and other separately payable and packaged drugs and biologicals at ASP plus six percent.<sup>32</sup> As is the case now, CMS would not make separate payment for “policy-packaged” drugs (contrast agents, diagnostic radiopharmaceuticals, anesthesia drugs; drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure and drugs; and biologicals that function as supplies when used in a surgical procedure).

Significantly, CMS proposes to adopt an alternative payment methodology for separately-payable drugs without pass-through status that hospitals purchase under the 340B drug discount program. CMS proposes for these drugs to be reimbursed at ASP minus 22.5 percent instead of ASP plus six percent.<sup>33</sup> CMS proposes to specifically exclude from this proposal drugs with pass-through status and vaccines (that already are excluded from the definition of 340B covered outpatient drugs).<sup>34</sup> Because CMS cannot currently identify 340B drugs in Medicare OPPS claims data, it also proposes to adopt a modifier, to be effective January 1, 2018, for hospitals to report when submitting claims for separately payable drugs “*not acquired* under the 340B program.” CMS would assume that the remaining OPPS drugs were purchased through the 340B program.<sup>35</sup>

CMS cites “several recent studies and reports on Medicare Part B payments for 340B purchased drugs [that] highlight a difference in Medicare Part B drug spending between 340B hospitals and non-340B hospitals as well as varying differences in the amount by which the Part B payment exceeds the drug acquisition cost” as background to this decision.<sup>36</sup> CMS acknowledges a Medicare Payment Advisory Commission (MedPAC)

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<sup>30</sup> *Id.* at 33,610.

<sup>31</sup> *Id.* at 33,610-18.

<sup>32</sup> *Id.* at 33,632.

<sup>33</sup> *Id.* at 33,634.

<sup>33</sup> *Id.* at 33,631-34.

<sup>34</sup> *Id.*

<sup>35</sup> *Id.* at 33,633-34.

<sup>36</sup> *Id.* at 33,632.

Report to Congress from May 2015 finding “that, on average, hospitals in the 340B program ‘receive a minimum discount of 22.5 percent of [ASP] for drugs paid under the [OPPS].”<sup>37</sup>

In addition, CMS cites a May 2016 MedPAC report including data from the Office of the Inspector General (OIG) stating that the average savings across all 340B providers, both hospitals and grantees, is 33.6 percent of ASP.<sup>38</sup> In this report, MedPAC recommended that Medicare pay hospitals at ASP minus 10 percent, and the OIG had recommended payment alternatives ranging from ASP with no add-on payment to the 340B ceiling price plus six percent.<sup>39</sup> CMS also notes that the 340B program has grown over the years as additional background to its decision to adopt an alternative payment methodology.

CMS has chosen to assume an average discount for 340B-acquired drugs of 22.5 percent because it cannot determine the exact 340B ceiling price because those data are confidential, and CMS wants to continue to protect this confidentiality.<sup>40</sup> Note CMS appears to have accounted for participation in the 340B prime vendor program (PVP), under which participating 340B covered entities may receive additional discounts negotiated by the 340B prime vendor, in its determination that a 22.5 percent reduction will not exceed the discounts that hospitals actually are receiving through the 340B program.<sup>41</sup> These additional 340B payment adjustments would be included in the budget neutrality adjustments under the Social Security Act and would not be subject to the budget neutral scalar.<sup>42</sup> CMS also is asking for comment on whether it should apply the savings achieved through this payment adjustment to increasing payments for other services in general or specific services or providers, such as those treating a large share of indigent patients, under the OPPI for CY 2018.<sup>43</sup>

Finally, CMS requests comment on the validity of the basis for its decision to adopt this payment adjustment, whether it should consider a different payment rate, whether the proposal should be phased in over time, and ways to better identify the payment rates for 340B drugs in future, which vary across hospitals, including potentially requiring 340B hospitals to report their acquisition costs and charges for 340B drugs. CMS also asks for comment on whether there should be exceptions to this payment rate granted to certain hospitals, whether certain drugs, such as clotting factor, should be excluded from the payment adjustment, and whether hospital-owned or affiliated ASCs should have access to 340B drugs.<sup>44</sup>

(6) Proposals regarding drug administration services

a. *Proposed packaging of Level 1 and Level 2 drug administration services*

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<sup>37</sup> *Id.*

<sup>38</sup> *Id.*

<sup>39</sup> *Id.* at 33,633.

<sup>40</sup> *Id.* at 33,634.

<sup>41</sup> *Id.*

<sup>42</sup> *Id.*

<sup>43</sup> *Id.*

<sup>44</sup> *Id.*

CMS currently excludes packaging of low-cost drug administration services with a geometric mean cost of less than or equal to \$100 from the ancillary services packaging policy. CMS proposes to change that policy by packaging Level 1 drug administration (APC 5691) and Level 2 drug administration (APC 5692) services when these services are performed with another separately payable service, but paying for them separately when performed alone. CMS believes that conditional packaging of drug administration services would promote equitable payment between physician offices and hospital outpatient departments. CMS proposes to continue to pay vaccine administration services separately, because preventive services are excluded from the packaging policy.<sup>45</sup>

CMS also seeks comment about whether it should conditionally or unconditionally package all drug-administration services add-on codes, how it could incorporate the varied clinical drug protocols that result in different infusion times into a drug administration service add-on code payment proposal, and other recommendations on an encounter-based payment approach for drug administration services that are described by add-on codes in the hospital outpatient setting.<sup>46</sup>

*b. Proposed payment rates for drug administration services*

A chart comparing the current 2017 drug administration payment rates to the proposed CY 2018 drug administration payment rates is provided below.

**Comparison of Hospital OPPS Drug Administration Rates, July 2017 to Proposed 2018**

HCPCS Code	Short Descriptor	Proposed 2018 Rates			Q3 2017 Rates			% Change 2017-2018
		SI	APC	Payment Rate	SI	APC	Payment Rate	
90461	Im admin each addl component	B			B			
90471	Immunization admin	Q1	5692	56.24	S	5692	53.17	5.77%
90472	Immunization admin each add	N			N			
90473	Immune admin oral/nasal	Q1	5692	56.24	S	5692	53.17	5.77%
90474	Immune admin oral/nasal addl	N			N			
96360	Hydration iv infusion init	S	5693	184.16	S	5693	179.77	2.44%
96361	Hydrate iv infusion add-on	S	5691	35.73	S	5691	34.78	2.73%
96365	Ther/proph/diag iv inf init	S	5693	184.16	S	5693	179.77	2.44%
96366	Ther/proph/diag iv inf addon	S	5691	35.73	S	5691	34.78	2.73%
96367	Tx/proph/dg addl seq iv inf	S	5692	56.24	S	5692	53.17	5.77%
96368	Ther/diag concurrent inf	N			N			
96369	Sc ther infusion up to 1 hr	S	5693	184.16	S	5693	179.77	2.44%
96370	Sc ther infusion addl hr	S	5691	35.73	S	5691	34.78	2.73%
96371	Sc ther infusion reset pump	Q1	5692	56.24	S	5692	53.17	5.77%
96372	Ther/proph/diag inj sc/im	Q1	5692	56.24	S	5692	53.17	5.77%

<sup>45</sup> *Id.* at 33,585.

<sup>46</sup> *Id.*

96373	Ther/proph/diag inj ia	S	5693	184.16	S	5693	179.77	2.44%
96374	Ther/proph/diag inj iv push	S	5693	184.16	S	5693	179.77	2.44%
96375	Tx/pro/dx inj new drug addon	S	5691	35.73	S	5691	34.78	2.73%
96376	Tx/pro/dx inj same drug adon	N			N			
96379	Ther/prop/diag inj/inf proc	Q1	5691	35.73	S	5691	34.78	2.73%
96401	Chemo anti-neopl sq/im	Q1	5692	56.24	S	5692	53.17	5.77%
96402	Chemo hormon antineopl sq/im	Q1	5692	56.24	S	5692	53.17	5.77%
96405	Chemo intralesional up to 7	Q1	5692	56.24	S	5692	53.17	5.77%
96406	Chemo intralesional over 7	S	5693	184.16	S	5693	179.77	2.44%
96409	Chemo iv push snl drug	S	5693	184.16	S	5693	179.77	2.44%
96411	Chemo iv push addl drug	S	5692	56.24	S	5692	53.17	5.77%
96413	Chemo iv infusion 1 hr	S	5694	286.62	S	5694	279.45	2.57%
96415	Chemo iv infusion addl hr	S	5692	56.24	S	5692	53.17	5.77%
96416	Chemo prolong infuse w/pump	S	5694	286.62	S	5694	279.45	2.57%
96417	Chemo iv infus each addl seq	S	5692	56.24	S	5692	53.17	5.77%
96420	Chemo ia push technique	S	5694	286.62	S	5694	279.45	2.57%
96422	Chemo ia infusion up to 1 hr	S	5693	184.16	S	5693	179.77	2.44%
96423	Chemo ia infuse each addl hr	S	5691	35.73	S	5691	34.78	2.73%
96425	Chemotherapy infusion method	S	5694	286.62	S	5694	279.45	2.57%
96440	Chemotherapy intracavitary	S	5694	286.62	S	5694	279.45	2.57%
96446	Chemotx admn prtl cavity	S	5694	286.62	S	5694	279.45	2.57%
96450	Chemotherapy into cns	S	5694	286.62	S	5694	279.45	2.57%
96521	Refill/maint portable pump	S	5693	184.16	S	5693	179.77	2.44%
96522	Refill/maint pump/resvr syst	S	5693	184.16	S	5693	179.77	2.44%
96523	Irrig drug delivery device	Q1	5733	53.22	Q1	5733	54.55	-2.44%
96542	Chemotherapy injection	S	5693	184.16	S	5693	179.77	2.44%
96549	Chemotherapy unspecified	Q1	5691	35.73	S	5691	34.78	2.73%

(7) Payment for radiation therapy services

A chart comparing the current 2017 radiation therapy payment rates to the proposed CY 2018 radiation therapy payment rates is provided below.

**Comparison of Hospital OPPS Radiation Therapy Rates, July 2017 to Proposed 2018**

HCPCS Code	Short Descriptor	Proposed 2018 Rates			Q3 2017 Rates			% Change 2017-2018
		SI	APC	Payment Rate	SI	APC	Payment Rate	
76873	Echograp trans r pros study	S	5523	149.67	S	5522	112.73	32.8%
77280	Set radiation therapy field	S	5611	122.37	S	5611	117.59	4.1%
77285	Set radiation therapy field	S	5612	315.51	S	5612	311.57	1.3%
77290	Set radiation therapy field	S	5612	315.51	S	5612	311.57	1.3%

<b>77295</b>	3-d radiotherapy plan	S	5613	1158.79	S	5613	1066.24	8.7%
<b>77300</b>	Radiation therapy dose plan	S	5611	122.37	S	5611	117.59	4.1%
<b>77301</b>	Radiotherapy dose plan imrt	S	5613	1158.79	S	5613	1066.24	8.7%
<b>77321</b>	Special teletx port plan	S	5612	315.51	S	5612	311.57	1.3%
<b>77331</b>	Special radiation dosimetry	S	5611	122.37	S	5611	117.59	4.1%
<b>77332</b>	Radiation treatment aid(s)	S	5611	122.37	S	5611	117.59	4.1%
<b>77333</b>	Radiation treatment aid(s)	S	5611	122.37	S	5611	117.59	4.1%
<b>77334</b>	Radiation treatment aid(s)	S	5612	315.51	S	5612	311.57	1.3%
<b>77336</b>	Radiation physics consult	S	5611	122.37	S	5611	117.59	4.1%
<b>77338</b>	Design mlc device for imrt	S	5612	315.51	S	5612	311.57	1.3%
<b>77370</b>	Radiation physics consult	S	5611	122.37	S	5611	117.59	4.1%
<b>77371</b>	Srs multisource	J1	5627	7335.22	J1	5627	7455.99	-1.6%
<b>77372</b>	Srs linear based	J1	5627	7335.22	J1	5627	7455.99	-1.6%
<b>77373</b>	Sbrt delivery	S	5626	1635.59	S	5626	1651.29	-1.0%
<b>77401</b>	Radiation treatment delivery	S	5621	124.45	S	5621	114.35	8.8%
<b>77470</b>	Special radiation treatment	S	5623	511.67	S	5623	494.63	3.4%
<b>77520</b>	Proton trmt simple w/o comp	S	5623	511.67	S	5623	494.63	3.4%
<b>77522</b>	Proton trmt simple w/comp	S	5625	941.77	S	5625	994.12	-5.3%
<b>77523</b>	Proton trmt intermediate	S	5625	941.77	S	5625	994.12	-5.3%
<b>77525</b>	Proton treatment complex	S	5625	941.77	S	5625	994.12	-5.3%
<b>77750</b>	Infuse radioactive materials	S	5622	213.83	S	5622	204.51	4.6%
<b>77761</b>	Apply intrcav radiat simple	S	5623	511.67	S	5623	494.63	3.4%
<b>77762</b>	Apply intrcav radiat interm	S	5623	511.67	S	5623	494.63	3.4%
<b>77763</b>	Apply intrcav radiat compl	S	5624	694.43	S	5624	738.63	-6.0%
<b>77778</b>	Apply interstit radiat compl	S	5624	694.43	Q3	5624	738.63	-6.0%
<b>77789</b>	Apply surf ldr radionuclide	S	5621	124.45	S	5621	114.35	8.8%
<b>77799</b>	Radium/radioisotope therapy	S	5621	124.45	S	5621	114.35	8.8%

(8) Proposed treatment of new and revised CY 2018 Category I and III CPT codes

CMS received the CY 2018 CPT codes from the American Medical Association (AMA) that will be effective January 1, 2018 in time for inclusion in the Proposed Rule. These codes appear in Addendum B and are assigned to new comment indicator “NP” to indicate that the code is new for the next calendar year or the code is an existing code with substantial revision to its code description in the next calendar year with a proposed APC assignment and that comments will be accepted on the proposed APC assignment and status indicator. The long descriptors for these codes are available in Addendum O of the Proposed Rule. The final CPT code numbers will be included in the final rule.<sup>47</sup>

<sup>47</sup> *Id.* at 33,603.

(9) Proposed treatment of new CY 2018 Level II HCPCS and Category III CPT codes

CMS solicits comments on the proposed CY 2018 status indicators, APC assignments, and payment rates for 18 Level II HCPCS codes and 10 Category III CPT codes that were made effective April 1, 2017 and July 1, 2017. These codes are listed in Tables 13 and 14 of the Proposed Rule.<sup>48</sup>

(10) Care management coding changes effective January 1, 2018

CMS proposes CPT replacement codes for five care management services G-codes adopted last year.<sup>49</sup>

<b>CY 2017 HCPCS Code</b>	<b>CY2017 HCPCS Short Descriptor</b>	<b>Proposed CY 2018 Replacement CPT Code*</b>	<b>Proposed CY 2018 Replacement HCPCS Short Descriptor</b>	<b>Proposed CY 2018 OPPS SI</b>	<b>Proposed CY 2018 OPPS APC</b>
<b>G0502</b>	Init psych care Manag, 70min	994X1	1st psyc collab care mgmt	S	5822
<b>G0503</b>	Subseq psych care man, 60mi	994X2	Sbsg psyc collab care mgmt	S	5822
<b>G0504</b>	Init/sub psych Care add 30 m	994X3	1st/sbsq psyc collab care	N	N/A
<b>G0505</b>	Cog/func assessment outpt	99XX3	Assmt & care pln pt cog imp	S	5822
<b>G0507</b>	Care manage serv minimum 20	99XX5	Care mgmt. svc bhvl hlth cond	S	5821

\* These are five-digit placeholder CPT codes. The final CPT codes will be included in the CY 2018 OPPS/ASC final rule with comment period.

(11) Proposed changes to APCs

a. Creation of a new imaging APC

For CY 2018, CMS proposes to split existing APC 5524, Level 4 Imaging without Contrast, into two APCs and create new APC 5525, Level 5 Imaging without Contrast.<sup>50</sup> CMS explains that “the data support splitting the current Level 4 Imaging without Contrast APC into two APCs such that the Level 4 Imaging without Contrast APC would include high frequency low

<sup>48</sup> *Id.* at 33,601-03.

<sup>49</sup> *Id.* at 33,604.

<sup>50</sup> *Id.* at 33,608-09.

cost services and the proposed Level 5 Imaging without Contrast APC would include low frequency high cost services.”<sup>51</sup>

*b. Proposed APC exceptions to the 2 times rule*

CMS generally requires the highest cost item or service in an APC group to not be more than two times greater than the lowest cost one (i.e., the “2 times rule”). For CY 2018, CMS proposes exceptions from the 2 times rule for 12 APCs.<sup>52</sup>

<b>Proposed CY 2018 APC</b>	<b>Proposed CY 2018 APC title</b>
<b>5112</b>	Level 2 Musculoskeletal Procedures
<b>5161</b>	Level 1 ENT Procedures
<b>5311</b>	Level 1 Lower GI Procedures
<b>5461</b>	Level 1 Neurostimulator and Related Procedures
<b>5521</b>	Level 1 Imaging without Contrast
<b>5573</b>	Level 3 Imaging with Contrast
<b>5611</b>	Level 1 Therapeutic Radiation Treatment Preparation
<b>5691</b>	Level 1 Drug Administration
<b>5731</b>	Level 1 Minor Procedures
<b>5735</b>	Level 5 Minor Procedures
<b>5771</b>	Cardiac Rehabilitation
<b>5823</b>	Level 3 Health and Behavior Services

*(12) Changes to procedures that would be paid only as inpatient procedures*

For CY 2018, CMS proposes to remove the following two procedures from the inpatient only list:<sup>53</sup>

<b>CY 2018 CPT Code</b>	<b>Description</b>
<b>27447</b>	Arthroplasty, knee, condyle and plateau; medical and lateral compartments with or without patella resurfacing (total knee arthroplasty)
<b>55866</b>	Laparoscopy, surgical prostatectomy, retropubic radical, including nerve sparing, includes robotic assistance, when performed

CMS also solicits comments on whether it should remove the following additional two procedures from the inpatient only list:<sup>54</sup>

<b>CY 2018 CPT Code</b>	<b>Description</b>
<b>27125</b>	Hemiarthroplasty, hip, partial (eg, femoral stem prosthesis, bipolar arthroplasty)

<sup>51</sup> *Id.* at 33,609.

<sup>52</sup> *Id.* at 33,605.

<sup>53</sup> *Id.* at 33,643-45.

<sup>54</sup> *Id.* at 33,645.

<b>27130</b>	Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip arthroplasty)
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(13) Payment adjustments

a. *Cancer hospital payment adjustments*

CMS proposes to use a target payment-to-cost ratio (PCR) of 0.89 to determine the CY 2018 cancer hospital payment adjustment.<sup>55</sup> Eleven cancer hospitals currently receive this payment adjustment to reflect the greater costs incurred by these cancer hospitals as compared to other OPPS hospitals. This PCR reflects the requirement in the 21<sup>st</sup> Century Cures Act that the PCR adjustment be reduced by 1.0 percentage point than would otherwise apply.<sup>56</sup> Table 11 in the Proposed Rule provides the estimated percentage increase in OPPS Payments for CY 2018 due to payment adjustment for these eleven cancer hospitals.<sup>57</sup>

b. *Payment changes for film X-ray and computed radiography technology*

As is required by Section 502 of the Consolidated Appropriations Act of 2016, CMS proposes to implement a 20 percent reduction of payment for imaging services that are X-rays using film, as identified by the modifier “FX.”<sup>58</sup> CMS also proposes to implement a seven percent reduction of payment for imaging services that are taken using computed radiography technology, as identified by the modifier “XX,” furnished during CY 2018 through CY 2022, and a 10 percent reduction for those services furnished after CY 2023.<sup>59</sup> There would not be a payment reduction for a packaged X-ray service under either modifier.<sup>60</sup>

c. *Potential revisions to laboratory date of service policies*

The current Medicare laboratory date of service (DOS) requirements are used to determine when a hospital may bill Medicare for a clinical diagnostic laboratory test (CDLT) and when the laboratory performing the test may bill Medicare directly. When the DOS falls during an inpatient or outpatient stay, payment for the laboratory test (if ordered within 14 days of discharge) is usually bundled with the hospital service and not separately payable. Commonly referred to as the “14- day-rule,” stakeholders have expressed continued concerns to CMS regarding operational challenges created by the current laboratory DOS policy for hospitals and laboratories with respect to molecular pathology tests and advanced diagnostic laboratory test (ADLTs). For CY 2018, CMS is considering potential modifications to the DOS policy that would allow laboratories to bill Medicare directly for molecular pathology tests and ADLTs, as these tests may have a different pattern of clinical use than more conventional laboratory tests, which may make them generally less tied to a primary service in the hospital outpatient setting than more common and routine laboratory tests that are packaged. CMS is soliciting public comment on whether these tests may be separated

<sup>55</sup> *Id.* at 33,596.

<sup>56</sup> *Id.*

<sup>57</sup> *Id.*

<sup>58</sup> *Id.* at 33,649.

<sup>59</sup> *Id.* at 33,650.

<sup>60</sup> *Id.*



from the hospital stay that preceded the test and therefore should have a DOS that is the date of performance rather than the date of collection. CMS is also considering an alternative option under which the contemplated DOS rule exception would apply only to ADLTs and not molecular pathology tests. CMS seeks comments on these two potential exceptions to the “14-day-rule” and its application in the hospital outpatient setting.<sup>61</sup>

(14) Proposals regarding device-intensive procedures

a. *Proposal for HCPCS level device-intensive status and device edits*

CMS did not propose any changes in this section of the Proposed Rule. The list of device-intensive procedures is available in Addendum P.<sup>62</sup>

b. *OPPS payment adjustment for no cost/partial credit devices*

CMS did not propose any changes to no cost/full credit and partial credit devices.<sup>63</sup>

c. *Proposed payment policy for low-volume intensive procedures*

CMS proposes to continue to calculate the payment rate for low-volume device-intensive procedures at the median cost instead of the geometric mean cost. Low-volume device-intensive procedures are devices tied to a clinical APC with less than 100 claims for all procedures in the APC. CMS hopes this policy will reduce year-to-year rate fluctuations.<sup>64</sup>

(15) Payment for certain items and services furnished by certain off-campus provider based departments

For CY 2018, CMS does not propose to make any changes “to limit clinical service line expansion or volume increases” at excepted off-campus provider based departments (PBDs).<sup>65</sup> CMS does state, however, that it will “continue to monitor claims data for changes in billing patterns and utilization, and continue to invite public comments on this issue.”<sup>66</sup>

With respect to payment proposals, CMS refers readers to the CY 2018 Medicare Physician Fee Schedule proposed rule where the agency proposes to reduce the payment rates PBDs receive for non-excepted items and services by half, from 50 to 25 percent of the OPPS rates.<sup>67</sup>

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<sup>61</sup> *Id.* at 33652-53.

<sup>62</sup> *Id.* at 33,618-19.

<sup>63</sup> *Id.* at 33,619-20.

<sup>64</sup> *Id.* at 33,620-21.

<sup>65</sup> *Id.* at 33,658.

<sup>66</sup> *Id.*

<sup>67</sup> *Id.*; 82 Fed. Reg. 33,950, 33,982 (Jul. 21, 2017); see also Hogan Lovells Overview of Selected Provisions of the Medicare Physician Fee Schedule Proposed Rule for Calendar Year 2018.

(16) Enforcement Instruction for the Supervision of Outpatient Therapeutic Services in Critical Access Hospitals (CAHs) and Certain Small Rural Hospitals

For CY 2018, CMS is proposing to reinstate the nonenforcement of direct supervision enforcement instruction for outpatient therapeutic services for CAHs and small rural hospitals having 100 or fewer beds for CY 2018 and 2019. CMS's objective is to give CAHs and small rural hospitals having 100 or fewer beds more time to comply with the supervision requirements for outpatients therapeutic services and to give all parties time to submit specific services to be evaluated by the Advisory Panel on Hospital Outpatient Payment for a recommended change in the supervision level. The previous nonenforcement instruction, required by legislative action, expired on December 31, 2016.<sup>68</sup>

(17) Hospital Outpatient Quality Reporting Program

a. *Addition, removal, or delay of quality measures from the Hospital OQR Program measure set*

CMS proposes no new measures for the Hospital OQR Program. CMS proposes to remove a total of six measures.<sup>69</sup> Beginning with the CY 2020 payment determination, CMS proposes to remove:

- OP-21: Median Time to Pain Management for Long Bone Fracture, and
- OP-26: Hospital Outpatient Volume Data on Selected Outpatient Surgical Procedures.

Beginning with the CY 2021 payment determination, CMS proposes to remove:

- OP-1: Median Time to Fibrinolysis.
- OP-4: Aspirin at Arrival,
- OP-20: Door to Diagnostic Evaluation by a Qualified Medical Professional, and
- OP-25: Safe Surgery Checklist.

Starting with the CY 2020 payment determination, CMS proposes to delay:

- The Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey Based Measures OP-37a-e.

b. *Future measure topics*

CMS invites public comment on possible measure topics for future consideration in the Hospital OQR Program, particularly any outcome measures to add or any clinical process measures to eliminate.<sup>70</sup>

c. *Possible future adoption of the electronic version of OP-2: Fibrinolytic Therapy Received Within 30 Minutes of Emergency Department Arrival*

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<sup>68</sup> 82 Fed. Reg. 33,558, 33,649.

<sup>69</sup> *Id.* at 33,673.

<sup>70</sup> *Id.* at 33,678.

CMS requests public comment about the possible future development and adoption of a new electronic clinical quality measure (eCQM): OP-2: Fibrinolytic Therapy Received Within 30 Minutes of Emergency Department Arrival measure.<sup>71</sup>

*d. Public display of quality measures*

CMS proposes to begin public reporting of OP-18c (Median Time from Emergency Department Arrival to Emergency Department Departure for Discharged Emergency Department Patients- Psychiatric/Mental Health Patients), and to make associated technical (e.g., name) changes to related measures and to the form used to collect OP-18c in light of the public reporting of the measure.<sup>72</sup>

*e. Administrative requirements*

Starting with the CY 2020 payment determination, CMS proposes to change its Hospital OQR Program Notice of Participation (NOP) submission deadline, such that all participating hospitals would be uniformly required to submit a NOP any time prior to registering on the QualityNet website.<sup>73</sup>

*f. Form, manner, and timing of data submitted for the Hospital OQR Program*

Starting with the CY 2020 payment determination, CMS proposes that any hospital that did not participate in the previous year's Hospital OQR Program must, in order to participate, submit data beginning with encounters occurring during the first calendar quarter of the year prior to the affected annual payment update.<sup>74</sup>

*g. Hospital OQR Program validation requirements for chart-abstracted measure data submitted directly to CMS for the CY 2020 payment determination and subsequent years*

CMS policy is to review a random sample of 450 hospitals each year for validation purposes and to select an additional 50 hospitals for validation based on the hospitals' failure to meet validation requirements or the hospital's data submission having an outlier value for a reported measure. CMS proposes to clarify that it only targets outliers that reflect *poorer* scores relative to other hospitals. CMS also proposes to codify its validation policy, with this clarification, in regulation.<sup>75</sup>

*h. Proposed formalization and modifications to the educational review process for chart-abstracted measures validation*

Starting for the CY 2020 payment determination, CMS proposes to formalize its educational review process for hospitals that receive a validation score. CMS further proposes that, when the review indicates a CMS error against the hospital, CMS will correct the hospital's end of year Confidence Interval (CI) when review is timely requested of validation results

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<sup>71</sup> *Id.*

<sup>72</sup> *Id.* at 33,679.

<sup>73</sup> *Id.* at 33,679–80.

<sup>74</sup> *Id.* at 33,680.

<sup>75</sup> *Id.*

from the first three quarters of the year. For results from the fourth quarter, the reconsideration process must be used for CI corrections.<sup>76</sup>

*i. Extraordinary circumstances exception process for the CY 2020 payment determination and subsequent years*

CMS proposes to rename its “extraordinary circumstances extensions or exemptions” policy to the “extraordinary circumstances exceptions (ECE)” policy and make conforming changes to the relevant regulation.<sup>77</sup>

*(18) Ambulatory Surgical Center Quality Reporting (ASCQR) Program*

*a. New, removed or delayed quality measures from the ASCQR measure set*

CMS proposes to adopt three new measures for the ASQR Program. Starting with the CY 2021 payment determination, CMS proposes one new measure to be collected through a CMS web-based tool:

- ASC-16: Toxic Anterior Segment Syndrome<sup>78</sup>

Starting with the CY 2022 payment determination, CMS proposes two new measures:

- ASC-17: Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures, and
- ASC-18: Hospital Visits after Urology Ambulatory Surgical Center Procedures.<sup>79</sup>

CMS proposes to remove three measures for the CY 2019 payment determination and subsequent years:<sup>80</sup>

- ASC-5: Prophylactic Intravenous (IV) Antibiotic Timing,
- ASC-6: Safe Surgery Checklist Use, and
- ASC-7: ASC Facility Volume Data on Selected Procedures

Starting with the CY 2020 Payment Determination, CMS proposes to delay:

- ASC-15-a-e: OAS CAHPS Survey-based Measure.<sup>81</sup>

*b. Future measure topics*

CMS invites public comment on one specific possible future measure for inclusion in the ASCQR Program in a future rulemaking: The Ambulatory Breast Procedure Surgical Site Infection Outcome measure (National Quality Forum (NQF) #3025). CMS also seeks public comment on accounting for social risk factors in the ASCQR Program.<sup>82</sup>

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<sup>76</sup> *Id.* at 33,682.

<sup>77</sup> *Id.* at 33,683.

<sup>78</sup> *Id.* at 33,689.

<sup>79</sup> *Id.* at 33,695.

<sup>80</sup> *Id.* at 33,700.

<sup>81</sup> *Id.* at 33,701.

<sup>82</sup> *Id.* at 33,698.

c. *Form, manner, and timing of data submitted for the ASCQR Program*

CMS does not propose any changes with regard to its form, manner, and timing policies for submission of ASCQR Program data.<sup>83</sup> This includes no changes to CMS's minimum threshold, minimum case volume, and data completeness policies for claims-based measures using QDCs.<sup>84</sup>

CMS does, however, propose to remove two measures from CMS's online data submission tool, if CMS finalizes its above-discussed proposal to remove certain measures from the ASCQR Program.<sup>85</sup>

CMS also proposes to expand its online tool to allow for batch submissions beginning with data submitted during CY 2018 for the CY 2020 payment determination and subsequent years. Batch submission would allow data from multiple facilities to be submitted simultaneously using a single electronic file submitted through one agent QualityNet account.<sup>86</sup>

d. *Extraordinary circumstances exception process for the CY 2020 payment determination and subsequent years*

CMS proposes to rename its "extraordinary circumstances extensions or exemptions" policy to the "extraordinary circumstances exceptions" for the Hospital OQR Program, beginning January 1, 2018, and to revise its regulations to reflect this change.

(19) Medicare site-of-service price transparency

Under section 4011 of the 21<sup>st</sup> Century Cures Act, enacted on December 13, 2016, beginning in 2018, the Secretary is required to make available to the public a searchable website that includes the estimated payment amount for items and service under the OPPS and ASC payment systems, along with the estimated beneficiary liability for such items and services. CMS anticipates that the website will be made available in early CY 2018 and states that further details about the website will be issued through CMS's sub-regulatory process.<sup>87</sup>

(20) Request for information and public comments

Reflecting its commitment to considering broader changes to the Medicare program, CMS included within the Proposed Rule a Request for Information (RFI), seeking feedback from the public regarding potential "regulatory, subregulatory, policy, practice, and procedural changes" that would maintain flexibility and efficiencies in the Medicare program while reducing unnecessary burdens for clinicians, other providers, and patients and their families.<sup>88</sup> The agency indicated that submissions in response to the RFI could highlight ideas such as payment system redesign and minimizing reporting, monitoring, and

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<sup>83</sup> *Id.* at 33,700.

<sup>84</sup> *Id.*

<sup>85</sup> *Id.*

<sup>86</sup> *Id.* at 33,701.

<sup>87</sup> *Id.* at 33,648.

<sup>88</sup> *Id.* at 33,704

documentation requirements; and CMS specifically requested ideas regarding ways to incentivize the provision of screenings, assessments, and evidence-based treatment for individuals with opioid use disorder.<sup>89</sup>

Separately, CMS requested public comment on transparent ways to identify and eliminate inappropriate payment differentials for similar services that are provided in the inpatient and outpatient settings.<sup>90</sup> Finally, the agency requested public comment on the appropriate role of physician-owned hospitals in the delivery system, and the impact of the physician self-referral law, as currently enacted, on physician-owned hospitals.<sup>91</sup>

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<sup>89</sup> *Id.*

<sup>90</sup> *Id.*

<sup>91</sup> *Id.*