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September 6, 2013

**BY ELECTRONIC SUBMISSION**

Marilyn Tavenner
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Comments CMS-1600-P

Dear Administrator Tavenner:

On behalf of LUGPA, we thank you for the opportunity to comment on the Medicare Revisions to Payment Policies Under the Physician Fee Schedule, Clinical Laboratory Fee Schedule & other Revisions to Part B for CY 2014 proposed rule (CMS-1600-P), published in the July 19, 2013 Federal Register (the "Proposed Rule"). As set forth below, our principal concern is with the threat posed to the integrated care model by CMS's proposal to cap payment rates for more than 200 physician services at outpatient prospective payment system ("OPPS") or ambulatory surgery center ("ASC") rates (the "OPPS/ASC Cap"). We believe the proposed OPPS/ASC Cap is seriously misguided and should be withdrawn in its entirety.

In addition to the overall impact on the integrated, comprehensive care model, we are specifically concerned about the effect that the OPPS/ASC Cap would have on reimbursement for CPT code 88120, which is recorded where manual fluorescence in situ hybridization (FISH) is performed for urine specimen. As you know, urine specimen FISH is universally recognized to be an important diagnostic and cancer management tool for physicians who treat Medicare beneficiaries with bladder cancer or suspected bladder cancer. LUGPA believes that the proposed cut in reimbursement to CPT code 88120 would jeopardize beneficiary access to this noninvasive, risk-free and convenient diagnostic tool that is almost always performed in a physician office. We demonstrate in this comment letter why, even if CMS were to implement the proposed OPPS/ASC Cap, CPT code 88120 should be exempt from the Cap. Finally, we show why there is no rationale for the significant disparity that continues to exist between lower reimbursement for manual FISH performed for urine specimens and higher reimbursement for manual FISH performed for all other specimens.

# I. Background

## A. LUGPA

In 2008, when physician leaders of large urology practices began to recognize the need for a formal association to help meet the challenges of the future, LUGPA was established with the purpose of enhancing communication between large groups, allowing for benchmarking of operations, promoting quality clinical outcomes, developing new business opportunities, and improving advocacy in the legislative and regulatory arenas. LUGPA currently represents 121 large urology group practices in the United States, with more than 2,000 physicians who make up more than 20 percent of the nation's practicing urologists.

Large urology practices are able to monitor health care outcomes and seek out medical "best practice" in an era increasingly focused on medical quality and the cost-effective delivery of medical services, as well as better meet the economic and administrative obstacles to successful practice. LUGPA's mission is to provide urological surgeons practicing within the context of large group practices the means to access resources, technology, and management tools that will enable them to provide all services needed to care for patients with acute and chronic illnesses of the genitourinary system in an efficient, cost-effective, and clinically superior manner, while using data collection to create parameters that demonstrates quality and value to patients, vendors, third party payors, and regulatory agencies.

Over the past several years, LUGPA has taken an active role in providing CMS and other governmental agencies, including the Medicare Payment Advisory Commission (MedPAC) and the Government Accountability Office (GAO), critical data and other information regarding diagnostic and therapeutic modalities used in providing care to our patients. On numerous occasions, LUGPA representatives have met with senior leaders in all of these agencies, as well as with members of Congress, to discuss peer-reviewed and other empirical studies of the utilization of various modalities for treating prostate cancer in Medicare beneficiaries. In addition, LUGPA has provided comments to CMS on the Medicare Shared Savings Program/Accountable Care Organizations proposed rule and regarding FISH testing, which is the focus of our comments below.

We hope to continue the relationship we established with CMS, MedPAC, GAO, and others by providing meaningful commentary to agency reports, inquiries, and proposals. In that vein, we provide the following comments on CMS-1600-P.

## B. Fluorescence *in situ* Hybridization

### 1. Definition and Use

*In situ* hybridization is a cytogenetic technique used to detect and localize the presence or absence of specific DNA sequences on chromosomes. Fluorescence *in situ* hybridization ("FISH") uses a specific protein, called a probe, that has been designed to "stick" to unique DNA in a cell. Probes are fluorescent and bind to only those parts of a

chromosome with which they show a high degree of sequence similarity.[1] FISH can be performed on blood, tissue, tumor, bone marrow, or urine samples, and is used to detect a variety of cancers and genetic abnormalities. Depending on the cancer or condition for which the test is performed, FISH generally requires the use of two or more probes and, in some cases, in excess of 12 probes.

With respect to bladder cancer, FISH has been shown to be "a rapid, simple, and powerful [diagnostic] tool for an improved identification of bladder cancer in bladder washings and in voided urine specimens."[2] Results from FISH from urine specimens "can help monitor responses and predict the risk of progression in patients with superficial bladder cancer,"[3] potentially reducing the need for invasive cystoscopic evaluations in the management of patients with the disease. The FISH test performed to identify bladder cancer involves the use of four probes, each of which is labeled with a different fluorescent dye and identifies a particular chromosomal abnormality.

### 2. Coding and Billing

Prior to the implementation of the CY 2011 PFS, all FISH was coded and billed using CPT codes 88365, 88367 and 88368, with the appropriate CPT code listed one time for each probe used in the performance of the test. For example, in a typical panel, FISH for detecting Non-Hodgkin's Lymphoma involves five probes while Multiple Myeloma involves 14 probes. Thus, the supplier would bill the appropriate CPT code five times for the test for Non-Hodgkin's Lymphoma and 14 times for the test for Multiple Myeloma. Until the adoption of the CY 2011 PFS, the medium of the specimen (*i.e.*, blood, tissue, tumor, bone marrow, or urine) was not relevant, as the supplies, clinical labor, equipment, and physician work are not affected by the specimen medium.

For CY 2011, the Medicare PFS final rule with comment period included two new cytopathology codes that relate solely to FISH testing of urine specimens:

> 88120—Cytopathology, *in situ* hybridization (e.g., FISH), urinary tract specimen with morphometric analysis, 3-5 molecular probes, each specimen; manual
>
> 88121—Cytopathology, *in situ* hybridization (e.g., FISH), urinary tract specimen with morphometric analysis, 3-5 molecular probes, each specimen; using computer-assisted technology

These codes were adopted by the American Medical Association's ("AMA") CPT Editorial Panel and accepted by CMS for the Medicare PFS. Based on discussions with both CMS and a member of the AMA's Specialty Society Relative (Value) Update Committee ("RUC"), it is LUGPA's understanding that the new codes were not

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[1] O'Connor, C. (2008) Fluorescence in situ hybridization (FISH). *Nature Education* 1(1).

[2] Bubendorf L, Grilli B, Sauter G, et al. Multiprobe FISH for enhanced detection of bladder cancer in voided urine specimens and bladder washings. *Am J Clin Pathol*. 2001; 116:79-86.

[3] Kipp B, Karnes J, Brankley S, et al. Monitoring intravesicle therapy for superficial bladder cancer using fluorescence in situ hybridization. *J Urol*. 2005;173:401-404.

generated at the specific request of CMS under initiatives related to misvalued codes, nor were they established at the request of the RUC through its identification of services that are frequently billed together or in multiple units. Rather, the request for the new code development likely originated with a specialty society, such as the College of American Pathologists. We note that no new codes were developed for FISH performed on any other specimen type (*i.e.*, blood, tissue, tumor, or bone marrow).

## II. The Proposed OPPS/ASC Cap Threatens the Integrated Model of Care, Is Seriously Misguided and Should Be Withdrawn in its Entirety.

CMS proposes that for certain CPT codes (including, but not limited to CPT code 88120 for manual FISH testing), when the amount paid under the PFS for a service is higher than what is paid for that same service under the OPPS (or, if applicable, ASC rates), it would adjust the PE RVUs under the PFS so that the amounts paid are equal under both payment systems .[4] LUGPA recognizes that CMS has received extensive comments from stakeholders across physician specialties and, indeed, across the entire health care industry expressing great concern about the proposed OPPS/ASC Cap. Although the primary focus of our comment letter is on the mistaken application of the OPPS Cap to CPT code 88120, we believe it is important to highlight our general concerns with the proposed cap.

**The proposed OPPS/ASC Cap threatens the very existence of the integrated model of care available in physician offices.** There can be no question that an integrated approach to patient care streamlines services to produce better health outcomes. Yet, the proposed OPPS/ASC Cap jeopardizes the types of integrated, comprehensive models of care that CMS advances through its Center for Medicare and Medicaid Innovation and other agency-sponsored demonstration projects. It has been widely cited that 82 percent of the codes on the cap list have direct expenses which exceed the proposed payment cap amount, making them unsustainable in the office setting. We note that none of the critical services that LUGPA's members have integrated into their group practices has been spared—whether they be pathology, diagnostic imaging or radiation oncology services. CMS should not finalize a proposal that, at its core, is so fundamentally at odds with the promotion of an integrated model of care.

**We do not believe that CMS has provided an adequate rationale for this dramatic change in payment methodology.** CMS spent over two decades developing the PFS, yet the agency provides no basis for rejecting the data it has used for more than 20 years and switching its payment methodology for certain services to rely on rates developed under another, wholly dissimilar payment system. CMS simply may not abandon the values developed under the statutorily-prescribed PFS because it prefers the rates established under another payment system. Further, if CMS truly believes that the OPPS or ASC rates better reflect costs in the physician office setting, then it also should have proposed to *raise* reimbursement under the PFS when the PFS rate is lower than the corresponding OPPS or ASC rate. CMS has made no such proposal here. Rather, CMS would use the proposed approach only to lower payments when the PFS rate is higher than the OPPS or ASC rate. This is evidence of the arbitrary nature of CMS's proposal.

[4] 78 Fed. Reg. 43282, 43296 (July 19, 2013) (CMS 1600-P).

**It is inappropriate to compare a CPT code payment under the PFS with an ambulatory payment classification ("APC") payment under the OPPS.** The PFS and the OPPS are two entirely different payment systems, as CMS recognized in the OPPS Proposed Rule for CY 2014.[5] While the PFS provides for a separate payment for each coded line item, the OPPS groups similar services together into bundled payments. In the hospital setting, the bundling approach may underpay for certain services but overpay for other services, enabling hospitals to make up for losses on one service with profits on another service. This is not the case for unbundled payments under the PFS. Furthermore, the problem is compounded under the PFS, because CMS is *not* proposing to increase payments where the PFS rate is lower than the rate paid under the OPPS.[6]

**The flaws in the proposed cap policy are compounded by limiting 2014 PFS rates based on a comparison to 2013 OPPS and ASC rates.** The inequitable nature of the proposed OPPS/ASC Cap is further demonstrated by the fact that rates paid under the 2014 PFS will not take into account anticipated payment updates that have been proposed for CY 2014 for the OPPS and ASC payment structures. This will only further exacerbate the disparity between the OPPS/ASC Cap applicable to PFS rates in the coming year and the actual amounts to be paid in the hospital and ASC settings. It strikes us as wholly arbitrary of CMS to cap reimbursement for certain services under the PFS at rates that CMS is simultaneously modifying for the hospital and ASC settings.

In summary, we urge CMS to withdraw its proposal to cap payments for certain CPT codes under the PFS at corresponding OPPS and ASC rates. The basis for this approach is both unsound and arbitrary, if not outside the scope of CMS's statutory authority.

## III. At a Minimum, CPT Code 88120 Should be Exempt from the OPPS Cap.

As explained above, LUGPA believes that the proposed OPPS/ASC Cap is misguided and should be withdrawn in its entirety. However, even if the proposed cap is implemented, it should not be applied to CPT code 88120. To do so, would be inappropriate for three distinct reasons.

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[5] *See* 78 Fed. Reg. 43533, 43569 (July 19, 2013) ("OPPS Proposed Rule") (acknowledging that the OPPS' prospective payment system is "not intended to be a fee schedule, in which separate payment is made for each coded line item" and stating that CMS's goal is to make OPPS payments for all services paid under the OPPS "more consistent with those of a prospective payment system and less like those of a per-service fee schedule").

[6] In addition to our concern about how the proposed cap would impact reimbursement for CPT code 88120 (*see* Part III below), we are also concerned with the impact that the cap policy would have on certain urology-related codes to be capped at ASC rates. CPT codes 11983, 50200, 50384, 50386, 50592, 50593, 51101, 51702, 51726, 51727, 51728, 51729, 51784, 51785 and 53855 cover urology services performed in the facility and physician office settings. CMS's proposal would cap payment amounts for each of these 15 codes at ASC rates. In each instance, the capped rate would not cover the supply costs for these services in the physician office setting. Moreover, as the American Urological Association noted in its public comment letter, eight of the 15 codes should have been exempted from the proposed cap policy because the codes are billed less than five percent of the time in the facility setting. *See* Public Comment Letter from David Penson, MD, MPH, Chair, Health Policy Council, American Urological Association to CMS Administrator Tavenner at 3-4 & Addendum A (Sept. 3, 2013).

First, we believe CPT code 88120 was erroneously excluded from the list of codes exempt from the OPPS Cap due to the fact that the code is billed less than five percent of the time in the hospital (facility) setting. It appears to us that CPT code 88121, the code recorded where FISH testing is performed with the assistance of a computer, is exempt from the OPPS Cap for this reason.[7] We doubt that the method for the FISH test (*i.e.*, manual or computer-assisted) would have any significant effect on its billing frequency in the hospital (facility) setting, especially given that the CPT code has been in existence for only three years of the PFS payment cycle (CY 2011, CY 2012, and CY 2013).[8]

Second, the substantial payment disparity between the APCs to which CPT code 88120 (manual FISH testing for urine specimen) and CPT code 88368 (manual FISH testing for all other specimen) map further illustrates the flaw in subjecting CPT code 88120 to the OPPS Cap.[9] Because LUGPA member practices are not paid for FISH testing services under the OPPS, we have not previously had a reason to review or comment on this inappropriate payment differential, which is similar to the differential in payment for CPT codes 88120 and 88368 under the PFS and, we suspect, equally unsupported.

In light of the proposed OPPS Cap, we must now object to the inappropriately low payment for CPT code 88120 under the OPPS and the corresponding inappropriately low proposed cap on the PFS payment for this service for CY 2014. The problem is exacerbated by the proposed downgraded APC assignment for CPT code 88120 for CY 2014. The code has been reduced from Level V pathology in CY 2013 ($157.05) to Level III pathology for CY 2014 ($144.39), while an increase in payment to $277.56 has been proposed for APC 344 (CPT code 88368). There is no rational basis for the payment disparity between these nearly identically-resourced services—a point on which we focus in Part IV below when comparing the two codes under the PFS.

Third, although we recognize that the Medicare PFS results in reimbursement for services that is not based on the cost of furnishing a particular service, we remain concerned that reimbursement levels for manual FISH for urine specimen remain well below the direct and indirect costs associated with furnishing the test. We have drawn CMS's attention to this disparity dating back to our first letter to CMS on the subject in January 2011.[10] The application of the proposed OPPS/ASC Cap to CPT code 88120 would create an even wider gulf than in past years between reimbursement for manual FISH for urine specimen and the significantly higher supply and labor costs associated with the test. For CY 2014,

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[7] As CPT codes 88120 and 88121 both map to ambulatory payment classification ("APC") 661 under the CY 2013 OPPS, the only reason we can ascertain for exempting CPT code 88121 from the OPPS Cap under the Proposed Rule is the infrequency of billing for the service in the hospital (facility) setting.

[8] Our doubts about the applicability of the OPPS Cap to CPT code 88120 are validated by the recent public comment filed by the American Clinical Laboratory Association ("ACLA"), which noted that CMS has informally indicated that CPT code 88120 should not have been included among the CPT codes subject to the proposed OPPS Cap. *See* Public Comment Letter from Alan Mertz, President, American Clinical Laboratory Association to CMS Administrator Tavenner at 3 n.5 (Aug. 29, 2013).

[9] For CY 2013, the payment for APC 661 (Level V pathology)—to which CPT code 88120 mapped—was $157.05, while the payment for APC 344 (Level IV Pathology)—to which CPT code 88368 mapped—was $241.80.

[10] *See* Letter from Raoul S. Concepcion, M.D., President, LUGPA to Donald Berwick, M.D., Administrator, CMS, Comment to CY 2011 MPFS Final Rule, CMS-1503-FC (Jan 3. 2011) at 4-5.

CMS proposes to assign 4.65 RVUs for the technical component ("TC") of CPT code 88120. Applying the CY 2013 conversion factor ("CF") as a proxy for the not yet finalized CY 2014 CF, the CY 2014 PFS payment for the TC would be $158.21. LUGPA member group practices from the Northeast, Mid-Atlantic, Midwest, and West report that the direct raw supply and clinical labor inputs required to furnish the TC of CPT code 88120 would be as high as $420.00 or 265% of the estimated proposed CY 2014 PFS payment for the service.[11]

Notwithstanding the growing disconnect between cost and reimbursement, LUGPA member practices have remained committed to finding a way to continue offering this critical diagnostic test. We are concerned, however, that the application of the proposed OPPS Cap to CPT code 88120 would be a bridge too far and would result in many existing suppliers ceasing to furnish urine specimen FISH, eliminating what is universally recognized to be an important diagnostic and cancer management tool for physicians who treat Medicare beneficiaries with bladder cancer or suspected bladder cancer. To compound the problem, without access to this painless, safe test, beneficiaries will be required to undergo invasive cystoscopy procedures with their attendant risk and increased financial liability (through facility and physician service copayments).

For these reasons, LUGPA respectfully requests that CMS withdraw the proposed OPPS/ASC Cap in its entirety or, at a minimum, exclude CPT code 88120 from the list of pathology codes subject to the proposed OPPS Cap.

## IV. Disparity Between the Reimbursement for Manual FISH Performed on Urine Specimens and Manual FISH Performed on All Other Specimens Violates the Principles Underlying the Medicare PFS.

As published in the Proposed Rule, CPT code 88120 was assigned 6.31 total RVUs. CPT code 88368, the code from which CPT code 88120 is cross-walked, was assigned 3.61 total (fully implemented) RVUs.

**Chart A – RVUs for CPT Codes 88120 and 88368**

| CPT Code | Physician Work RVUs | Practice Expense RVUs | Malpractice RVUs | Total RVUs |
|---|---|---|---|---|
| **88120 (1-5 probes)** | 1.20 | 5.05 | 0.06 | 6.31 |
| **88368 (each probe)** | 1.40 | 2.16 | 0.05 | 3.61 |

Applying the CY 2013 conversion factor (CF) of $34.023 for consistency sake (and ignoring application of the proposed OPPS Cap), a four-probe urine specimen manual

[11] We note that these projections are consistent with the survey results from the ACLA-commissioned study by The Moran Company (included as an attachment to ACLA's publicly filed comment letter), which showed that the mean costs incurred by survey responders in performing manual FISH testing for urine specimen (CPT code 88120) was 259% of the mean OPPS cost findings ($422.94 versus $163.18). *See* Public Comment Letter from Alan Mertz, President, American Clinical Laboratory Association to CMS Administrator Tavenner (Aug. 29, 2013) at Attachment, Appendix B.

FISH would be reimbursed for CY 2014 at $214.68 (6.31 x $34.023), while a four-probe blood specimen manual FISH would be reimbursed at $491.29 (3.61 x $34.023 x 4 probes) (ignoring geographic practice cost adjustments). Put another way, urine specimen manual FISH would be reimbursed under CPT code 88120 at only 43.7 percent of the reimbursement for other media specimens under CPT code 88368.[12] LUGPA continues to take issue with this disparity.

There is no significant work or practice expense differential between FISH performed on urine specimens and FISH performed on other specimen types. As you know, the Medicare PFS is a resource-based, relative value system (RBRVS). The underlying principle of this system is that procedures that utilize similar resources and physician effort should be reimbursed similarly. In practice, nearly identical supplies, clinical labor, and equipment are used regardless of the medium of the specimen analyzed. Despite this, the PE inputs for CPT codes 88120 and 88368 have very little overlap (as shown in Chart B on the next page). As we have pointed out in the past, it is clear that urine specimen manual FISH receives inequitable treatment under the PFS as compared to that of non-urine manual FISH, which is simply inconsistent with the RBRVS that CMS is mandated by statute[13] to utilize in establishing Medicare payments under the PFS.[14]

It is logical to assume that the practice expense inputs for CPT codes 88120 and 88368, particularly with respect to supplies and labor, would be virtually the same, if not identical. Yet, inexplicably, the CPT codes are assigned drastically different direct PE inputs and quantities for essentially the same service. As Chart B shows, there are 12 practice expense inputs for CPT code 88120, only four of which it shares with CPT code 88368, and there are nine direct PE inputs for CPT code 88368, only four of which its shares with CPT code 88120.[15] Given the drastically different direct PE inputs for CPT codes 88120 and 88368—codes that describe essentially the same service (and were billed under the same code prior to CY 2011)—we respectfully request that CMS reevaluate the direct PE inputs assigned to the codes to ensure consistent inputs are used for both CPT codes 88368 and 88120.

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[12] As discussed in Section II above, in the Proposed Rule, CMS is proposing that, when the amount paid under the PFS for a service is higher than what is paid for that same service under the OPPS, CMS would adjust the Practice Expense RVUs under the PFS so that the amounts paid are equal. Because CPT code 88120 and CPT code 88368 would be subject to the OPPS Cap if CMS finalizes its proposal as published, this Part IV compares only these two FISH CPT codes to ensure an equal and accurate comparison.

[13] *See* Section 1848 of the Social Security Act; Pub. L. 101-239 and Pub. L. 101-508.

[14] Even if one assumes that the existing FISH CPT codes are over-valued, it is incomprehensible that reimbursement for urine specimen manual FISH (88120) would be set 56.3 percent lower than reimbursement for other media specimen manual FISH (88368).

[15] It is our understanding that CMS has not revisited the direct PE inputs for CPT code 88368 for a number of years.

**Chart B – PE Inputs for CPT Codes 88120 and 88368**

| | | 88120 Non-Facility Time | 88368 Non-Facility Time |
|---|---|---|---|
| | | CY 2014 | CY 2014 |
| EP007 | centrifuge (with rotor) | 2.22 | 0 |
| EP008 | cytology thinlayer processor (ThinPrep) | 0.22 | 0 |
| EP019 | hood, ventilator with blower | 5.94 | 0 |
| EP024 | microscope, compound | 1 | 41 |
| EP027 | microscope, fluorescence | 0 | 41 |
| EP030 | pH conductivity meter | 2.67 | 6 |
| EP041 | microtome | 0 | 3 |
| EP042 | vacuum pump | 0.89 | 0 |
| EP045 | chamber, hybridization | 0 | 240 |
| EP048 | microfuge, benchtop | 0.11 | 1 |
| EP049 | oven, isotemp (lab) | 0 | 1 |
| EP051 | slide warmer | 0 | 10 |
| EP054 | water bath, FISH procedures (lab) | 2.11 | 13 |
| EP088 | ThermoBrite | 321 | 0 |
| EP089 | Camera (Olympus DP21) | 7 | 0 |
| EP092 | Olympus BX41 Fluorescent Microscope (without filters or camera ) | 73 | 0 |
| EP093 | Filters | 73 | 0 |

Further, LUGPA believes that the physician work input for urine specimen manual FISH testing (30.00) should be adjusted to compare more closely with the input associated with other specimen media for FISH testing (45.00 per probe, or 180.00 for the four probes required for urine specimen FISH testing). We respectfully urge CMS to increase the physician work input amount for CPT code 88120 to match the physician work input amount for CPT code 88368 when billed for four probes.

In summary, the vast payment differential between CPT codes 88120 and 88368 is not consistent with the RBRVS. We respectfully requested in past comment letters that CMS reverse its adoption of CPT codes 88120 and 88121. Although CMS has not done so, in the CY 2013 PFS Final Rule, CMS indicated that the RUC would evaluate the possibility of developing other specimen-specific codes (e.g., for blood, tissue, etc.) to ensure the appropriate relativity between urine FISH testing and non-urine FISH testing.[16] There is no evidence in the Proposed Rule that such exploration has occurred. Given the continued disparity between the reimbursement for manual FISH performed on urine specimens and manual FISH performed on all other specimens, we respectfully request that: (1) CMS adjust the PE inputs, physician time inputs, and RVUs assigned to CPT

[16] 77 Fed. Reg. 68892, 69059 (Nov. 16, 2012) (CMS-1590-FC).

code 88120 to recognize the similarity between manual FISH testing on urine specimens and manual FISH testing on all other specimen media; and (2) CMS continue to work with the RUC to explore the possibility of developing other specimen-specific codes.

## V. Summary

The proposed OPPS/ASC Cap poses a serious threat to the integrated model of care in which LUGPA's member practices furnish care to Medicare beneficiaries. We believe the proposed cap is seriously misguided and should be withdrawn in its entirety. In particular, LUGPA urges CMS not to apply the OPPS Cap to reimbursement for urine specimen manual FISH (CPT code 88120), because of the devastating effect that the OPPS Cap would have on this important diagnostic and cancer management tool used by physicians who treat Medicare beneficiaries with bladder cancer or suspected bladder cancer. Moreover, CPT code 88120 should be exempt from the cap because it is billed less than five percent of the time in the hospital (facility) setting. Finally, as we demonstrated to CMS in prior comments and again today, there is no medical basis for treating urine specimen FISH testing different than FISH testing using any other type of specimen. Doing so violates the principles that underlie the Medicare RBRVS for reimbursement under the PFS. As a result, CMS should adjust the inputs and RVUs assigned to CPT code 88120 to recognize the similarity between this code and CPT code 88368 and also consider the adoption of codes specific to other types of specimens on which FISH can be performed.

On behalf of LUGPA, we appreciate the opportunity to comment on the Proposed Rule. Please feel free to contact me at (516) 342-8170 or dkapoor@impplc.com, or Howard Rubin at (202) 625-3534 or howard.rubin@kattenlaw.com, if you have any questions or if LUGPA can provide additional information to assist CMS as it considers these issues.

Respectfully submitted,

Deepak A. Kapoor, M.D.
President

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