The Council on Radionuclides and Radiopharmaceuticals, Inc.

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HEALTH CARE POLICY, NUCLEAR PHARMACY, & SPECIAL INTEREST ON CONTRAST AGENTS COMMITTEE

Draft Minutes (1-25-18)

Monday, December 4, 2017, 11:00 am – 5:00 pm (*Lunch from 12:30 pm- 1:00 pm)*
Offices of Reed Smith, 1301 K Street, NW
Washington, DC, Conference Rooms 10 H & 10 I
Dial-In Number: 1-800-730-9938; Access Code: 4149241

I. Welcome The meeting was called to order by HPC and NPC Co-chairs Paul Knapp, and Mike Rossi. Also Nick Zerbi and Jesse Johnson were in attendance and Adrienne Shipps and Jack Slosky participated via conference call. Moreover, a copy of the attendance sheet is attached.

II. Antitrust Guidance
Andy Bernasconi, Reed Smith, CORAR antitrust counsel addressed the members of the committee and reminded them of CORAR's antitrust policy, their obligations as CORAR Members, and the potential repercussions to them, the association and their companies in the event of non-compliance. Counsel remained with the Committees through the Committee's deliberations.

III. Approval of Minutes of previous meeting
The Minutes of the previous meeting (May 3, 2017) were considered and approved by the Committees.

IV. Guest Welcome and Comments
CORAR welcomed the guests in attendance. Each guest was recognized for a few remarks. The comments are summarized below:

NANP: Jeff Norenberg commented that this was the 10th year that NANP has been invited to attend the open session of the CORAR HCP and NP Committee Meetings. NANP is collaborating with the National Association of Boards of Pharmacy (NABP) on the development of an MOU (between states and the FDA) regarding interstate shipments of compounded drugs. NANP continues to monitor state boards of pharmacy to ensure

compounder compliance to USP Chapter <797>. It was mentioned that an Expert Panel has been created to develop a separate chapter (USP Chapter 825) for Nuclear Pharmacy Practice. Finally, NANP plans to hold it annual meeting at the APhA meeting in Nashville, March 16th through 18th.

ASNC:

Kathy Flood reported that ASNC (in conjunction with ACR and the SNMMI) had succeeded in advocating for a change in the First Coast Services Options (FCSO) Local Coverage Decision (LCD) for Cardiac PET. The change in the LCD aligns FCSO's LCD with the National Coverage Decision (NCD) for Cardiac PET. Kathy mentioned that the American Medical Association's Current Procedural Terminology Editorial Panel has approved a category III billing CPT code for PET absolute quantitation of myocardial blood flow, this will be effective Jan. 1, 2018.

Also, ASNC is monitoring the HeartFlow®, Inc. Fractional Flow Compouted Tomography application. HeartFlow is a portfolio company of the Blue Cross Blue Shield Venture Partners. The Blues cover this technology and beginning January 1, 2018, Centers for Medicare & Medicaid Services (CMS) has finalized a New Technology Ambulatory Payment Classification (APC) for the HeartFlow® FFRct Analysis. Under the APC payment system, hospitals enrolled in Medicare that bill CMS for the HeartFlow FFRct Analysis for Medicare patients will be eligible for reimbursement at a rate of $1,450.50 for the technical component of the test.

Finally, some additional points Kathy made include that the Appropriate Use Criteria mandate (under PAMA) has been delayed another year, to 2020; ASNC will continue with outreach and education on nuclear cardiology to referring physicians. Image Guide Registry has grown to 100 sites and ASNC has joined with the American Society of Echocardiography to build an echo registry model, and 2018 will be the 25th anniversary of ASNC.

SNMMI:

Dr. Bennet Greenspan (current SNMMI President) described the three to five years goals under the SNMMI Value Initiative. The goals are aligned under: Quality of Practice, Research and Discovery, Workforce Pipeline & Lifelong Learning, Advocacy, Outreach, and Organizational Strength & Stability.

Dr. Greenspan mentioned the SNMMI Appropriate Use Criteria (AUC) that have been completed include Amyloid Imaging (2013), Bone Scintigraphy in Prostate and Breast Cancer (2017), Ventiliation/Perfusion (V/Q) imaging in Pulmonary Embolism (2017), Hepatobiliary Scintigraphy in Abdominal Pain (2017), FDG PET/CT Restaging and Response Assessment of Malignant Disease (2017), and Somatosstatin Receptor PET Imaging in Neuroendocrine Tumor Imaging (2017).

SNMMI is currently working on AUCs for PET Myocardial Perfusion Imaging (MPI), Gastrointestinal Transit, Infection Imaging, Prostate Cancer Imaging, and Nuclear

Medicine in the Diagnosis and Treatment of Thyroid Cancer (to include I-123 & I-131 tracers). Additional AUCs will be developed in 2018.

MITA:

Sue Bunning discussed several major areas that MITA is focused on including demonstrating value of PET imaging to support increased clinical adoption of the technology. Also, MITA is focused on removing reimbursement barriers to imaging and is working with CORAR, and other stakeholders to advocate for separate payment of diagnostic radiopharmaceuticals under the Hospital Outpatients Prospective Payment system.

MITA partnered with ASNC on a Cardiac PET webinar and is continuing to work with private payers to demonstrate the value of PET imaging This includes the continued efforts by MITA to request that CMS remove the Non-Coverage Decision (NCD) for all PET Imaging. Finally, MITA has concerns with the use of the "JW" Modifier with regards to contrast.

AAPM:

Richard Martin stated that AAPM is focused on ensuring patient and provider access to radioisotopes. Also, the AAPM is participating in the Source Security Working Group.

Nuclear Pharmacy and Healthcare Policy Regulatory Issues & Priorities
(Paul Knapp, Mike Rossi, Nick Zerbi, Alan Kirschenbaum, Michael Guastella)

A. State enforcement against copycats – CORAR state letter updates:

   There was no new updates or additional information to share with the Nuclear Pharmacy Committee.

B. Radiopharmaceutical Compounding Guidance:

   We had no new information from FDA on the progress and timing of the release of radiopharmaceutical compounding guidance. Later in the week, Julie Dohm from FDA followed up with CORAR (via email response) on our request for a status report and she stated, "*I, unfortunately, do not have any update to share, except that we are working on these guidances.*"

C. FDA Response Letter to JDI Citizen's Petition:

   Mike Rossi reviewed the FDA response in which they denied that it permits nuclear pharmacies and outsourcing facilities to engage in activities similar to manufacturers but under lesser standards. FDA responded that "to the extent the requested actions in the JDI CP constitute a request to address the production by nuclear pharmacies and outsourcing facilities of radiopharmaceutical drugs that are essentially copies of FDA-approved commercially available

radiopharmaceuticals…we grant those requests through the issuance of two draft guidances that, ***when final***, will describe FDA's policies regarding compounded radiopharmaceuticals that are essentially copies of approved radiopharmaceuticals."

It is encouraging to note that FDA's granting of this part of the JDI CP depends upon the finalization of the two draft RP compounding guidances (listed above), and the phrase "***when final***" also indicates that FDA plans to finalize these guidances. It seems unlikely that FDA would have responded to the CP in this manner if the Agency had any doubt (whether because of a Trump executive order or otherwise) that the guidances will be finanized;

D. Proposed USP Chapter <825> for Nuclear Pharmacy Practice:

It was reported that an Expert Panel has been constituted to develop this new chapter. The timeline requires that final draft of USP Chapter <825> be completed for review and approval at the next USP meeting (2020). A list of Expert Panel members was discussed and will be provided to CORAR for distribution to the full committee.

E. FDA June 5th, 2017 Radiopharmaceutical Compounding Listening Session:

CORAR attended this Listening Session where FDA asked for the top items the attendees wanted to discuss. Those items were FDA Draft Guidance on Insanitary Conditions at Compounding Facilities; Beyond Use Dating; Harmonization of FDA guidance with USP standards; the 10% criteria for determination of an essential copy; terminology regarding the use of compounding and minor deviations; industry concerns on radiopharmaceutical copy-cat activity and inordinate interstate shipment.

CORAR focused comments on the criteria for the determination of an essential copy in the draft nuclear pharmacy guidance and stated our opposition to the use of a fixed 10% maximum difference in radioactive dose to determine whether a compounded radiopharmaceutical is a copy of an approved product. We mentioned that this created a loop-hole and would potentially allow unscrupulous nuclear pharmacies to avoid the prohibition on essential copies merely by increasing or decreasing the radioactivity by slightly more than the established percentage.

Also, CORAR encouraged FDA to add to the nuclear pharmacy guidance a prohibition on interstate shipments of compounded radiopharmaceuticals "that involve manipulations other than minor deviations."

It was mentioned to the committee that some Listening Session participants had endorsed that the criteria for the determination of an essential copy of a radiopharmaceutical not include the requirement that the drug be included in the

FDA Drug Shortage List. CORAR did not support this comment.

F. December 2017 Nuclear Pharmacy and HCP-Regulatory Committee Priorities and Action Items:

a) In the January/February 2018 timeframe, CORAR will begin work to formally comment to FDA on the necessity to expedite the release of radiopharmaceutical compounding guidance. When possible, reference in this communication other stakeholder requests for action including the JDI Citizen's Petition.
b) Consider adding to the FDA comment letter, referenced above, any additional compounding pharmacy radiopharmaceutical copy-cat activities – if proof can be forwarded to CORAR.
c) If proof of additional copy-cat activity is obtained, also consider developing a complaint letter to the South Carolina Board of Pharacy and Medicaid Fraud Control Unit.
d) Follow-up communication with BOPs and MFCUs regarding the State copycat letters in first quarter of 2018;
e) Nuclear Pharmacy Committee will continue to monitor the USP process for the development of general chapter <825> and determine if any committee action is required.

V. Special Interest Committee on Contrast Agents

(Adrienne Shipps, Jack Slosky, Courtney Johnson, Alan Kirschenbaum, Michael Guastella)

A. November 30th CORAR FDA meeting to provide drug manufacturer perspective of the FDARA legislation § 706:

a) A good representation of CORAR members participated in this meeting (both in person at the FDA and through the conference call bridge). Dr. Marzella started the meeting with CORAR following up and reinforcing that CORAR represents primarily drug companies. Therefore, our perspective is drug based.

Alan Kirschenbaum provided CORAR's view of what § 706 accomplishes by pointing out three aspects of the problem:
Can device and drug labeling be inconsistent, and, if so, when?
What type of application should the device company submit?
What data must the device company submit to obtain clearance/approval?

It was mentioned by CORAR that this is largely a device problem. It was pointed out that FDARA § 706 answers the first question by giving FDA the authority, under certain conditions of "sameness" to clear/approve a device when the drug labeling is inconsistent. It was

reinforced that the conditions of "sameness" do not include indications for use changes of the drug.

Section 706 does not address the second question and does not provide any direction on what kind of data the device company should provide.

FDA encouraged CORAR to consider further engagement with the agency on this topic and potentially collaborate with MITA on a joint meeting with FDA.

VI. Health Care Policy (HCP) Committee – Review Progress on 2017 Priorities
(Jesse Johnson, Nick Zerbi, Gail Daubert, Jim Massie, Courtney Johnson, Michael Guastella)

A. Dx RP Separate Payment Legislative Strategy Activities Update:

a) Members of MITA, SNMMI, and CORAR participated in a November 2nd Hill Day fly-in to advocate for separate payment of Dx Radiopharmaceuticals (RPs) under the CMS Outpatient Propsepctive Payment System;
b) Congresswoman Brooks and Congressman Moulton have agreed to be sponsors of the CORAR proposed Dx RP separate payment legislation;
c) Industry and Society stakeholders will now focus on engaging potential sponsors on the Senate Finace Committee as well as the House Ways and Means Committee.

B. 2018 Final OPPS rule – update on payment policyfor diagnostic radiopharmaceuticals under HOPPS:

a) CMS will continue to policy-package diagnostic RPs, without substantive policy revisions;
b) OPPS rates will increase by 1.35%; overall payments will increase by 1.4% considering all policies;
c) CMS will maintain the same four nuclear medicine ambulatory payment classifications (APC). CMS did not adopt its proposal to add a fifth APC level for imaging without contrast;
d) CMS will continue the add-on payment policy for radioisotopes produced from non-highly enriched uranium for 2018 without change;
e) The 2018 OPPS drug packaging threshold is $120, compared to $110 for CY 2017.

C. Medicare Contractor fee schedules for Dx RPs:

a) It was noted that AmeriHealth Medical Policy has packaged diagnostic PET agents in with the procedure in the freestanding imaging setting. CORAR Counsel suggested that this was just one example and that

CORAR may want to consider reviewing and commenting on local MAC and commercial carrier payment methodologies for Dx RPs.

D. December 2017 HCP-Reinbursement Committee Priorities and Action Items:

a) Continue to collaborate with SNMMI, MITA, ACR, and ASNC to build broader support for proposed legislation to support appropriate federal government reimbursement for Dx RPS under HOPPS:

a) Continue to discuss with key Congressional offices the legislative language (and one-pager) that proposes a $500 separate payment threshold for Dx RPs under HOPPS;
b) Continue to stay focused on separate payment for Dx RPs under HOPPS only and not include additional items such as radiopharmaceutical edits (on claims) and expanded transitional pass-through;
c) Continue to work with with CORAR member companies that are willing to engage their Congressional Delegations in support of our legislative strategy;
d) Continue Hill meeting after the first of the year.

b) Provide comments to the 2019 proposed and final HOPPS and MPFS rules regarding radiopharmaceuticals.

VII. Special Interest Committee (SIC) on Contrast Agents (Closed Session)
(Adrienne Shipps, Jack Slosky, Michael Guastella)

A. With funding completely exhausted and no commitment by one of the two SIC member companies to provide additional funding, the future of the SIC on Contrast Agents was discussed with several options presented to the HCP Committee. A commitment was made to discuss these options at the upcoming CORAR Board Meeting.

VIII. Adjourn – motion and second

IX. Next Meeting – May 14, 2018