DRAFT 1
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The Council on Radionuclides and Radiopharmaceuticals, Inc.

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

Monday, May 2nd, 2016, 1:00 pm – 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 Jesse Johnson, Paul Knapp, and Mike Rossi. Also Adrienne Shipps, Co-Chair of the SIC on Contrast Agents was in attendance in person and Jack Slosky was in attendance by phone. 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 (December 9, 2015) 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:

ACR: ACR discussed their March 3rd, 2016 proposal to CMS to consolidate and collapse imaging APCs (including nuclear medicine) under the Hospital Outpatient Prospective Payment System (OPPS) beyond the current structure. ACR provided comments on their rationale to approach CMS which included the fact that the ACR leadership believes that comprehensive Ambulatory Payment Classifications (APCs) are on the horizon for imaging and believe it is important to engage CMS now. The ACR proposal would result

in a slight aggregate decrease in government reimbursement for nuclear medicine procedures under the OPPS.

SNMMI: Besides the work on HOPPS payment reform for diagnostic radiopharmaceuticals, SNMMI continues to focus on Appropriate Use Criteria, FDA approval process, and radiation safety. Also, the SNMMI conducted their annual Spring Hill Day on May 2nd and the topics of discussion with Hill staff included the reliable supply of Mo-99 and appropriate government reimbursement for all diagnostic radiopharmaceuticals under the OPPS.

MITA: MITA reported that they will comment on the Part B Payment Model proposal from CMS and will advocate that transitional pass through for diagnostic radiopharmaceuticals undet the OPPS should not be included. MITA will be conducting panels later this year with representatives from Medicare Administrative Contractors (MACs) and Radiology Benefit Managers (RBMs) to discuss reimbursement policies impacting Medicare Beneficiaries. MITA remains committed to the Industry Forum activities to inform government reimbursement on diagnostic radiopharmaceuticals and is in final stages of negotiating a proposal to survey hospitals and physicians regarding the impact of government reimbursement policies on Medicare Beneficiary access to care.

ASHP and APhA: FDA recently released three compounding guidance documents: a) Hospital and Health System Compounding Under FD&C Act; b) Facility Definition Under Section 503B of the FD&C Act; c) Prescription Requirements Under 503A of FD&C Act. The guidance documents address longstanding stakeholder questions about how FDA intends to exercise oversight of traditional compounding as well as compounding in the hospital/health-system setting.

The draft guidances unequivocally establish patient-specific prescriptions as the hallmark of 503A, stating that 503A exemption from the new drug requirements of the FD&C Act is contingent upon compounding only for individually identified patients pursuant to a valid prescription order thereby prohibiting compounding for office use under 503A, while carving out a narrow exception to the "prescription requirement" for certain hospitals and health systems within a one-mile radius.

NANP: The focus areas continue to be: legitimate compounding, regulation of nuclear pharmacies, and domestic medical isotope supply supported by the American Medical Isotope Production Act (AMIPA). NANP is supportive of all government efforts through AMIPA to ensure Mo-99 supply but are concerned that the timelines (envisioned in creation of the bill) have been pushed back and there are no assurances that domestic Mo-99 supply will ever be achieved.

NANP participated in the recent meeting of the USP Sterile Compounding Expert Committee where the the draft revision to USP Chapter <797> were discussed. It was reported that USP received approximately 8,700 comments during the public comment period. NANP advocates for a separate USP chapter on sterile compounding with a nuclear pharmacy.

V. Nuclear Pharmacy and Healthcare Policy Regulatory Issues & Priorities

(Paul Knapp, Mike Rossi, Tamara Mills, Alan Kirschenbaum, Michael Guastella)

A. Update on FDA Radiopharmaceutical Compounding Guidance

Since the December 2015 CORAR meeting, a clarification email on the stakeholder proposed definitions of radiopharmaceutical preparation and minor deviations was sent directly to Jane Axelrad. Jane reiterated that FDA is currently working on Radiopharmaceutical Compounding Guidance but would not offer when we might expect FDA to release the guidance. To keep our concerns top-of-mind with the FDA, the committee discussed additional options to follow-up with the agency.

B. Government regulatory enforcement against copycat drugs:

It was reported to the Nuclear Pharmacy Committee that the letters to the five **State Boards of Pharmacy** and **States Attorney's General** were sent in April. This was an action item from the December 2015 meeting with the objective of educating the State BOPs and AGs on potential copycat violations and include a request for enforcement action to cease copycat activities:

C. Manufacturing Tc-99m on PET cyclotrons under the guise of the practice of pharmacy.

The committee decided that no action was required at this time and would could to monitor.

D. Follow-Up on Kim Brandt (Finance Committee Chief Oversight Counsel) Meeting.

It was reported that Courtney Johnson and Michael Guastella met with Kim on April 8th. The meeting was cordial, however, it became clear that Kim believes that CMS will not put out a newsletter (or alert) to hospitals informing them that they may be receiving compounded unapproved drugs (i.e. radiopharmaceuticals) which could be problematic if they are seeking Medicare Paymen. Kim has communicated this to Mike Gill, however, NANP, mentioned in the NP Committee meeting that the still considers this an option.

Kim stated that it may be possible for a letter from Alexander and Hatch encouraging FDA and CMS to address the issue of unapproved drugs being produced, distributed, and inappropriately receiving government payment. Kim requested that we provide an update on the status of our requests with FDA.

E. April 2016 Compounding Guidance Released by the FDA:

CORAR Counsel reviewed the three FDA guidance documents released in April: a) Hospital and Health System Compounding Under FD&C Act; b) Facility

Definition Under Section 503B of the FD&C Act; c) Prescription Requirements Under 503A of FD&C Act.

The prescription requirement guidance says that FDA is adhering to provisions under 503A and requiring a patient to be identified on the prescription before dispensing, except for limited anticipatory compounding consistent with historical patterns. Regarding office stock, the guidance says that if providers need to get non-patient specific compounds for office stock, they have to get them from a 503B outsourcing facility and applies only to 503A pharmacies.

The hospital and health system guidance says that a hospital or health system can compound a drug without a patient-specific prescription under 503A as long as it is only used for the health system's own patients and it is distributed only to facilities that are owned and controlled by the same health system and are within a 1 mile radius from the pharmacy. The 503B facility definition guidance says that a 503B outsourcing facility can't create a separate area for compounding under 503A and avoid cGMPs – the entire facility is subject to cGMPs.

F. May 2016 Nuclear Pharmacy Action Items:

1. As additional follow-up on our proposed 2015 revised Compliance Policy Guide submission to FDA, develop draft report language and have ready to go for an appropriate bill later this year. Also, follow up with Senate Help and Finance Oversight counsel regarding a letter from the HELP and Finance Committee Chairman reinforcing industry concerns on copy-cat radiopharmaceutical drugs and encouraging FDA to expedite release of radiopharmaceutical compounding guidance;
2. CORAR to consider whether to sign on to NANP letter to CDER and FDA Office of Compliance regarding two issues: supporting pharmacy sterile compounding regulation and pharmacy inspections being done by State Boards and reinforcing the need for FDA action regarding the manufacturing copies of FDA approved drugs under the guise of compounding. The letter is currently being drafted. After completion and receipt from NANP, Nuclear Pharmacy co-chairs to review and provide recommendation to the full Nuclear Pharmacy Committee on whether CORAR should sign on;
3. Nuclear Pharmacy co-chairs to review SNMMI USP 797 revision comment letter and determine if they will recommend to the full Nuclear Pharmacy Committee that CORAR should review and provide comments to SNMMI;
4. Deliver a 90-day follow-up communication (email was discussed) if necessary with the 5 BOPs and AGs regarding the State copycat letters;
5. Monitor MIDAC

VI. Health Care Policy Committee – Review Progress on 2016 Priorities

(Jesse Johnson, Tamara Mills, Gail Daubert, Jim Massie, Courtney Johnson, Michael Guastella)

A. Industry Forum Government Reimbursement Initiative:

1. The legislative fix options be considered by CORAR, MITA, and the SNMMI are:
    a) Separate payment for radiopharmaceutical drugs under HOPPS at the current threshold.
    b) Separate payment for radiopharmaceuticals under HOPPS with a different (higher) threshold.
2. The Industry Forum Legislative Fix strategy is expected to be completed after the results from the survey are received and evaluated. The results should quantify the patient access issues and help provide compelling evidence to support changes in government reimbursement policy for diagnostic radiopharmaceuticals.

B. Survey to determine HOPPS payment impact to Medicare Beneficiary access to certain nuclear medicine procedures.

1. MITA reported that they are working through NEMA to finalize a proposal for a survey. Expected to begin administering the survey instrument via email blast late Spring with the hope of receiving 300 – 350 email responses with 65 in-depth phone interviews conducted.

C. ACR proposed restructuring of Imaging APCs. Tis is reviewed in the ACR discussion above.

D. Reimbursement Question to Secretary Burwell – No formal written response has been provided by HHS at this time.

E. Medicaid Drug Rebate Program Final Rule

1. The final rule regarding the Medicaid Drug Rebate Program was released by CMS on February 1st, 2016. In the final rule, CMS clarifies that the definition of Covered Outpatient Drugs includes radiopharmaceuticals approved under a new drug application (NDA) or an abbreviated new drug application (ANDA)…
2. CORAR follow-up with CMS Medicaid regarding the radiopharmaceutical patient ready dose reporting strawman and base AMP proposal were requested.

F. CMS Proposed New Medicare Payment Model for Part B Drugs

1. CMS has released a complex and controversial plan to test new Medicare payment methods for certain Part B drugs to determine whether alternative payment designs will reduce Medicare expenditures while preserving or enhancing the quality of care provided to Medicare beneficiaries. CMS suggests that the current Medicare Part B drug

reimbursement framework — based on the drug's average sales price (ASP) plus 6 percent — provides a financial incentive to prescribe more expensive drugs without encouraging high-value care. To remove this incentive and promote value-based pricing, CMS is proposing to test a laundry list of reforms in selected geographic areas, such as basing payment on ASP plus a flat fee or incorporating a variety of value-based strategies used in many commercial plans.

2. The HCP Committee requested that CORAR comment with emphasis on the potential impact to new diagnostic radiopharmaceuticals under OPPS.

G. Update on Appropriate Use Criteria and Imaging

1. SNMMI provided an update on their progress in the development of nuclear medicine AUCs. The HCP Committee recognizes that this is an important topic and CORAR will continue to monitor.

H. May 2016 HCP Committee Priorities and Action Items:

1. Provide formal feedback to ACR on their CMS HOPPS proposal. Check with SNMMI and MITA to determine if there is an opportunity to collaborate on comments. Reinforce in our comments to ACR that we prefer to collaborate with other stakeholders on comments/proposals regarding HOPPS government reimbursement;
2. Provide email follow-up to Dr. McInness regarding the ACR proposal. Acknowledge that ACR shared the proposal with CORAR and our appreciation that Dr. McInness requested that ACR solicit feedback from the nuclear medicine community (including CORAR). Some key points in our comments to ACR include:
    a) CMS significantly collapsed the Nuclear Medicine APCs in 2016;
    b) Further changes to the HOPPS payment methodology could be premature since there is not data available to determine impact of the 2016 changes;
3. Continue to collaborate with Industry Forum government reimbursement committee on advocating appropriate government reimbursement which includes supporting the development of a survey to determine impact on HOPPS payment methodology on patient access;
4. Provide formal CORAR comments to CMS on proposed changes to drug payment methodology under Part B;
5. With final Medicaid Rebate Program Final Rule release, HCP Committee has requested that CORAR follow-up with CMS Medicaid regarding our 2012 strawman comments and Base AMP legal proposal.

VII. Special Interest Committee on Contrast Agents

(Adrienne Shipps, Jack Slosky, Alan Kirschenbaum, Gail Daubert)

A. Ongoing 2016 Goals of CORAR Contrast Agents SIC:

1. Support and promote goals and objectives of CORAR as Health Policy Committee Co-Chair
2. Represent interests of Contrast Imaging Drugs through reimbursement and regulatory advocacy
3. Actively recruit companies for SIC membership
4. Bayer and Lantheus are current members of SIC
5. Other members of CORAR are invited to join SIC
6. Prepare and present to CORAR Board analysis of SIC budget needs and member assessments

B. 2016 SIC on Contrast Agents Priorities and Action Items:

1. Remain involved in the APC reassignment activity, including providing recommendations;
2. Participation in conforming labeling discussions and F2F MITA and FDA meetings - Bayer and Lantheus directly involved;
3. Participate with MITA in meeting with FDA on May 27th to discuss proposed CORAR MITA conforming labeling language for contrast agents;
4. Provide contrast-related and modality specific comments to 2017 to-be-proposed Medicare payment rules;
5. Determine future of the SIC committee with evaluation results and board presentation scheduled for December 6, 2016.

VIII. 5:00 pm Adjourn

Meeting adjourned at 4:00 pm ET.