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HEALTH CARE POLICY, NUCLEAR PHARMACY COMMITTEES AGENDA

Monday, May 8, 2023, 11:00AM – 5:00 PM (EDT)

Offices of Reed Smith, 1301 K Street, NW

Washington, DC, Conference Rooms 10H & 10I

Zoom Conferencing: Zoom Information Provided Prior to Meeting

- I. Welcome and Introductions**
- II. Antitrust Guidance**
- III. Approval of November 14, 2022 HCP and NP Committee Meeting Minutes**
- IV. Guest Welcome and Comments**
 - A. AAPM, ACR, APhA, ASNC, ASTRO, MITA, NANP, SNMMI
- V. 12:00 PM – 12:30 Lunch**
- VI. Legislative Update (Courtney Johnson)**
- VII. 1:00 PM – 2:00 PM Nuclear Pharmacy Committee**

(Paul Knapp, Rick Wride, Alan Kirschenbaum, and Michael Guastella)

 - A. Status on USP <825>:
 - a. Nuclear Pharmacy Coalition (CORAR, APhA, NANP, & SNMMI) letter to State Boards of Pharmacy encouraging adoption of USP <825>.
 - b. State BOP implementation update.
 - c. Update on compendial status of USP <797> and <825>
 - B. Status of Concurrent Nuclear Pharmacy Coalition Letters to NABP and the State Boards of Pharmacy.
 - a. Additional actions

C. Monitoring Activities

- a. Radiopharmaceutical copycat regulatory enforcement efforts
- b. Preparation of FDA approved Ga-68 PET drug kits
- c. FDA Draft Guidance on Hospital Compounding by 503A Pharmacies

VIII. 2:00 PM – 3:00 PM Healthcare Policy Regulatory – Regulatory

(Michael Guastella, Alan Kirschenbaum, Nick Zerbi, and Mergime Dosku)

- A. Potential Revisions/Updates to Part 212.
- B. Appropriateness of Current FDA Regulations for Radiotherapy Manufacturers.
- C. Update on FDA implementation of FDARA §706.

IX. 3:00 PM – 3:30 PM – Break

X. 3:30 PM – 4:30 PM Healthcare Policy Committee – Government Reimbursement

(Nick Zerbi, Mergime Dosku, Gail Daubert, Jim Massie, Courtney Johnson, and Michael Guastella)

- A. Proposed HOPPS Dx RP Separate Payment Legislation - FIND Act of 2023 Update
 - a. Legislative Update
 - b. Administrative alternatives discussion
 - c. CBO simulation update
- B. CMS proposed rule regarding potential remedies for the Part B drug payment cuts for 340B disproportionate share hospitals
- C. Proposed CY 2024 OPPI and MPFS Rules

XI. Additional Business – No additional business was discussed.

XII. Adjourn

XIII. Closed Session

XIV. Next Meeting – December 11, 2023 at the Offices of Reed Smith, Washington, DC