To: CORAR Board of Directors

From: Lisa Saake
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Re: Report to Board of Directors of CORAR on the 2012 Priorities of the Health Care Policy Committee

Below, please find the Committee's priorities for 2012.

I. Health Care Policy Committee (Reimbursement) Priorities for 2012

a. Continue to support separate payment, as with traditional drugs, for diagnostic radiopharmaceuticals paid under HOPPS.

    i. Focus on gaining separate payment for new diagnostic radiopharmaceuticals. Also, continue to request separate payment for low volume/high cost diagnostic radiopharmaceuticals drugs whose costs are not appropriately captured in the bundled HOPPS APC Technical Component payment.
        1. Continued dialogue with CMS
        2. Participation in OSTP initiatives
        3. Legislative Efforts

b. Appropriate Treatment of Diagnostic Radiopharmaceuticals under Medicaid

    i. Seek to have CMS clarify reporting requirements for radiopharmaceuticals under the Medicaid program.

c. Develop and submit timely comments to both the 2012 proposed and final HOPPS and Medicare Physician Fee Schedule (MPFS) rules. Specifically monitoring and commenting on:

    i. Accuracy of proposed offsets for diagnostic radiopharmaceuticals paid under the HOPPS transitional pass through
    ii. Appropriate and accurate recognition of hospital overhead costs for radiopharmaceuticals within the HOPPS APC payments.
    iii. Accurate and appropriate HCPCS coding descriptor changes for radiopharmaceuticals
    iv. Changes to the technical component payment (capital equipment utilization assumption, interest rate assumption;
    v. Oppose inappropriate expansion of the multiple procedure payment reduction (50%) on single-session imaging to consecutive body parts.
    vi. Application of new IDTF certification requirements for physician office imaging.

d. Seek to extend transitional pass-through payment under Hospital Outpatient Prospective Payment System (HOPPS) to the full three year statutory limit for new radiopharmaceuticals. Also, seek appropriate payment methods and amounts for new diagnostic radiopharmaceuticals used in the physician office setting, as set by state and regional carriers

e. Support the option of manufacturer reporting of ASP for select diagnostic and therapeutic radiopharmaceuticals paid under the Medicare Physician Fee Schedule (MPFS).

   Some manufacturers have sought the option to voluntarily report ASP. CORAR may need to consider strategy where a legislative amendment is needed for CMS to enact. Possible benefits and repercussions should be considered and may be tested by starting with the Medicare Administrative Contractor (MAC) First Coast to test ASP basis for reimbursement.

f. Collaborate with industry partners and trade associations in revisions to the coverage for ***New*** PET Radiopharmaceuticals Paid under Medicare.

   i. Support modification of the current CMS National Non-Coverage Decision (NDC) for PET radiopharmaceuticals
   ii. Coordinate efforts with medical specialty and professional societies and groups including SNM, MITA, ACR, ASNC and AMI
   iii. Support accurate payments of existing PET radiopharmaceuticals under HOPPS in an effort to avoid significant year-to-year variation in Medicare APC payment amounts (best example continues to be cardiac PET

g. Monitor and comment on national and regional nuclear medicine procedure and radiopharmaceutical coverage and payment issues. This could include commenting on:
   i. Policies that limit patient access to nuclear medicine testing.
   ii. Inaccurate reimbursement of radiopharmaceuticals.

h. Monitor and comment on private payer developments of importance to nuclear medicine as well as coverage and payment of radiopharmaceuticals

i. Monitor and comment on federal implementation of the health care reform law focusing on provisions that impact medical imaging.

II. Health Care Policy Committee (Drug Review and Approval) Priorities for 2012

a. Re-establishment of the Medical Imaging Drug Advisory Committee (MIDAC)

   i. Monitor and publish to HCP members the final membership of MIDAC.
   ii. Monitor activities of MIDAC and provide feedback (positive and/or negative) to FDA to ensure FDA makes appropriate use of this advisory body and does

not decide to disband it. The regulatory co-chair will decide, based upon input from the members and status of the HCP budget, whether to ask counsel to attend the meeting on behalf of HCP.

b. Appropriate and Equitable Positron Emission Tomography (PET) User Fees

   i. Monitor generic drug user fee legislation to ensure the promised exemption is retained and take action if there is an indication it is not.
   ii. Monitor and protect the 1/6 user fee for PET facilities.
   iii. Monitor PUDFA V looking for opportunities or issues that would justify carefully engaging FDA for further reduction in PET establishment fees.

c. Special Exemption of Radiopharmaceuticals under Federal E-Pedigree Legislations

   i. Monitor legislative proposals that would grant FDA authority to require an e-pedigree, and, if necessary, meet with relevant Congressional staff to advocate an exemption for radiopharmaceuticals similar to the exemption we obtained in California's e-pedigree law. Note: Current draft legislation contains an exemption for radiopharmaceuticals that would include both kits and technetium generators.

d. Drug Shortage Legislation

   i. Continue interactions with FDA and legislators to ensure that the unique characteristics of radiopharmaceuticals are appropriately addressed in legislation as well as FDA regulations and guidance.
   ii. As relevant draft regulations and guidances are published we will review them and as appropriate provide comments on behalf of CORAR.

e. Strengthen Drug Safety and Import Legislation

   i. Continue to monitor the progress of drug safety legislation and engage Congressional staff as necessary to ensure relief from burdensome facility-based fees for radiopharmaceuticals, especially PET drugs.

f. Industry Input into the FDA's Medical Imaging Drug Guidances

   i. Monitor the Federal Register for FDA guidance of interest to CORAR members.
   ii. Provide summaries to HCP members and as appropriate compile and submit to FDA comments on behalf of CORAR.
   iii. Consider providing specific recommendations for revisions to the 3-part FDA guidance for Development of Medical Imaging Drugs.

g. HCP, NP and MQS Organizational Structure

i. Work with the chairs of the Nuclear Pharmacy committee to draft a reorganizational proposal for consideration by the HCP, NP and MQS membership and if agreed by the CORAR Board of Directors. The proposed reorganization would consider how best to structure the reimbursement, regulatory (drug, GMP, and pharmacy), manufacturing, and safety oversight activities of the three committees.

h. Potential Expansion of FDG Usage in Alzheimer's disease

i. While this may be of interest to a sub-group of CORAR members the resources required to pursue this are significantly greater than can be justified for CORAR as an organization. Individual members may want to pursue this individually or collectively, but it is not something that HCP can justify on their behalf.

ii. If the PET Working Group and/or the Society of Nuclear Medicine wish to continue pursuing this HCP may be willing to provide some assistance, but this is not identified as a specific goal for 2012. The regulatory co-chair will decide, based upon input from the members and status of the HCP budget, whether and what type of support is justified.