Setting Procedures to Usher in Reimbursements



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Spurring Collaboration!

How small, medium, and large NPCs are teaming up to solve systemic problems so we can all grow and thrive



Teaming up and Defining the Issue

The Basics:

- NPCs should be collecting funds and reimbursing their local VA for research-only activities
- The local VA should be billing their NPC for those costs
- VA Handbook 1200.17 11. b. (2)

Reimbursement. NPCs may reimburse VA for salaries and other costs incurred by VA in the conduct of VA-approved research projects or education activities. A VA medical facility may retain and use funds provided to it by a NPC. Such funds must be credited to the applicable VA appropriation account and available for account purposes without fiscal year limitations as provided for in 38 U.S.C. 7364(b)(3).

Not quite so simple...

Defining the Process and Steps

Pre-Study Activities

- MOU between VA and NPC
- Cost Basis provided by VA
- Methodology for incorporating costs into the study budget
- Cost Impact Forms and VA approvals
- Incorporating into NPC process, procedure

During Study

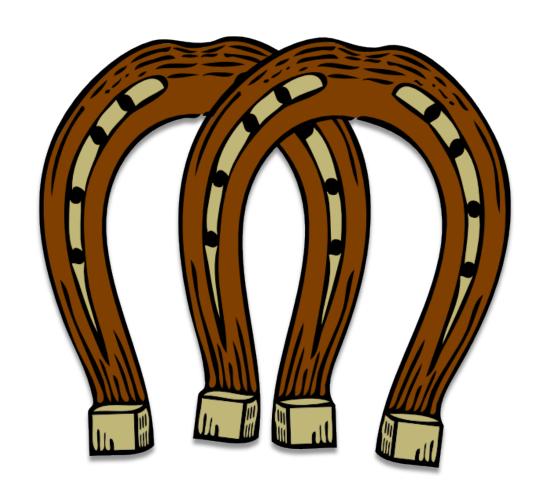
- Accurate, timely, and transparent accounting
- Regular reconciliation of study payments
- Internal designation of VA reimbursement amounts

Billing and Close-out

- Invoices issued by the VA
- NPC pays the bill in a timely fashion
- NPC reports expenditures on studies to R&D service for RDIS reporting
- Annual NPC reporting on total amounts reimbursed: NPPO?

Setting us up for Success!

Laying the groundwork for a successful billing process at each local NPC



MOU for Reimbursement of Research-Only Clinical Activities

Old MOUs

- Vague and unenforceable
- No timelines
- No cost basis defined
- No potential for enforcement
- No responsible parties defined
- No certifications
- No allowance for modification

New MOUs

- Clear language and format
- ► Timelines for billing, payment, and termination
- Definition of cost basis included
- Defined obligations
- Responsible parties defined
- Certification as to accuracy and applicability
- Terms for termination and amendment

MOU for Reimbursement of Research-Only Clinical Activities

Example Language

- 4. Resources that JBVAMC may furnish and seek reimbursement from [NPC] include the following:
 - a. Clinical services <u>furnished solely for research purposes</u>, e.g., laboratory, radiology/nuclear medicine, gastroenterology, cardiology or other tests or exams conducted as part of an approved research project;
 - b. Pharmacy services <u>furnished solely for research purposes</u>, e.g., study setup fees for clinical trials, dispensing fees, drug preparation fees, drug acquisition costs, etc.;
 - c. Personnel services costs to be billed at actual salary and benefits costs; and/or
 - d. Other goods and services which may, from time to time, be mutually beneficial.

Determination of Cost Basis

- Local VA Chargemaster
 - Costs for the facility or healthcare system, taking into account locality
- Medicare/Medicaid Tables
 - Some VA sites approve the use of discounted Medicare/Medicaid cost rates
 - Ex: Medicare less 20%
- Community Care Cost Tables- updated annually in January
 - Chargemasters used in fee-basis reimbursement and in billing third-party insurance for clinical activity not covered by a patients VA benefits
- Affiliate Chargemaster
 - CMS enacted an expansion on healthcare price transparency requirements. Effective January 1, 2019 hospitals are required to post their chargemasters publicly (but it doesn't require they make them easy to find, read, or interpret!)

Building Costs into the Study Budget

- Determine whether the Sponsor is presenting a budget that is total payment per patient, or that is itemized per procedure:
 - ► Ensure the amount offered covers all items listed in the study's Schedule of Events (found in the protocol)
 - If itemized, confirm that amounts offered for research-only clinical costs are adequate to reimburse VA for the service
- Confirm your VA costs reconcile with the cost basis in your MOU
- Lastly, ensure every cost item passes the "Reasonableness Test"

Cost Impact Forms and VA Approvals

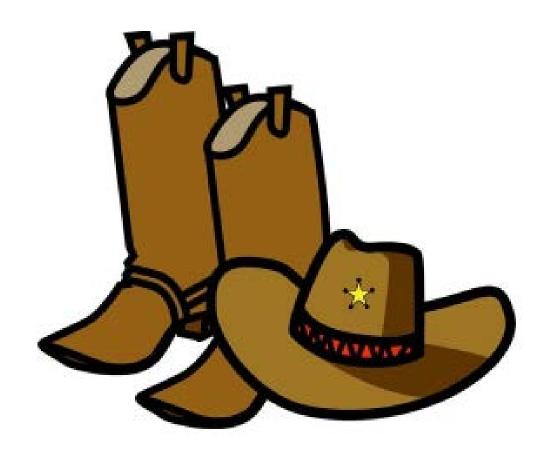
- Assessment of Cost Impact Forms are required for all VA-approved research
 - Suggested information to include:
 - Research activities to be performed
 - Estimated number of patients and/or activities
 - ► CPT code for the activity and it's related cost based on approved cost basis
 - Approval by the Chief of each affected service
- R&D Committee review and approval of the Cost Impact Form
 - Ratification by the Committee of the approved cost basis

Incorporating Process into NPC Policy

- Developing a Standard Operating Procedure within NPC policy to further detail the process.
- Flexibility in process- multiple options based on the local VA's willingness to work with the NPC
- Example: *

Doing Our Part!

Better bookkeeping, better oversight, better trials



Accurate & Transparent Accounting and Designating VA Reimbursements

- Best practices needed for keeping track of study activities through the duration of the study
 - Ensuring that information is readily available, adequately detailed, consistent from study to study, and follows the outlined MOU process
- Audience participation!
 - How do you account for funds owed to VA for research-only clinic costs? (even if they've never been billed)

Bringing it all Home!

When VA bills, we all win



Receiving a VA Bill

- Will VA track activities and provide a bill? If so...
- Work with your Research Service AO, establish relationships with the Fiscal Office and the other impacted Service Lines
 - Introduce them to the set up and appeal for their support
 - Remind AOs and leadership of the benefit of these returned monies, from supporting Continuing Education to supported travel to possible staffing
- Confirm itemized bill for accuracy (using agreed cost basis and cost impact form) and process payment
- If NPC is tracking the reimbursements- based on MOU, NPC will provide a detailed list of reimbursements along with a cover letter to fiscal requesting a bill be generated

Timely Payment of Invoices

- Confirm monies are available from each of the studies involved
- Generate check
- Achieve signatures
- Deliver to Agent Cashier
- File documentation of VA processing of check
- Include reimbursement in Annual Report and other reporting

Summary: Pre-Study Launch

- Establish a detailed Memorandum of Understanding between your NPC and the VA Medical Center with special attention to the key components:
 - Basis of costs to be reimbursed VA-generated vs. Medicare
 - Methodology "direct cost/services provided" vs. "percentage"
 - Timetable for reimbursement
 - Append the Clinical Impact Form Service Chiefs will sign to approve
- Work with PIs to confirm their budgets are constructed correctly, noting the reimbursement cost vs. the cost negotiated with the Sponsor
- Achieve signatures on the Clinical Impact Form and register with R&D Committee
- Diligently track expenditures on each project anticipating the tabulation and reporting required

Summary: Effecting Reimbursement

- Tabulate total costs incurred for each study to calculate amount to be reimbursed based on the cost basis from the MOU
- Present totals to PI for their review and approval; present approved totals to AOs of impacted Service Lines for their review and notice
- Depending on the system determined at your site
 - ▶ VA Bill of Collection: confirm amounts to identify any discrepancies; generate check
 - ▶ NPC-generated information: notice Fiscal Office of amounts involved; generate check
- Document VA processing of check for your records, reporting
- Report total amounts reimbursed in Annual Report, other reporting

Questions & Discussion- Thank you!



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