

March 11, 2011

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**Subject: *Clinical Research Billing Review
 Audit Project 2009-15***

The final audit report for Clinical Research Billing Review, Audit Report 2009-15, is attached. We would like to thank all UCSD personnel for their cooperation and assistance during the audit.

Because we were able to reach agreement regarding corrective actions to be taken in response to the audit recommendations, a formal response to the report is not requested.

The findings included in this report will be added to our follow-up system. We will contact you at the appropriate time to evaluate the status of the corrective actions. At that time, we may need to perform additional audit procedures to validate that actions have been taken prior to closing the audit findings.

UC wide policy requires that all draft audit reports, both printed (copied on tan paper for ease of identification) and electronic, be destroyed after the final report is issued. Because draft reports can contain sensitive information, please either return these documents to AMAS personnel, or destroy them at this time.

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AUDIT & MANAGEMENT ADVISORY SERVICES



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Clinical Research Billing Review
March 2011

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Project Number: 2009-15

Clinical Research Billing Review
Audit & Management Advisory Services Project 2009-15

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Executive Summary

Audit & Management Advisory Services (AMAS) has completed a review of selected clinical research billing processes as part of the approved audit plan for Fiscal Year 2009-10.

The objective of our review was to evaluate clinical trial charge entry and capture processes from the point of order to the allocation of charges to research bulk accounts or other patient accounts to determine whether research related services were directed to appropriate accounts in accordance with the study protocols, informed consents and/or related contracts.

Based on our audit procedures, we concluded that charges for research related services were not consistently directed to the appropriate patient account as defined by study protocols, informed consents and/or sponsor contracts. Several different manual or electronic test and procedure order processes were used. The complexity of certain aspects of the research charge capture process required the participation of a number of staff in various MC administrative and clinical service departments.

The current research charge capture and billing infrastructure does not support effective communication of study information and requires coordination and collaboration between departments that generally do not work together. Research processes and systems should be examined and analyzed to maximize integrity in conducting research and to establish accountability. Processes should be designed to manage and coordinate information to ensure that accountability for billing accuracy is clearly defined, and that research billing errors are prevented whenever possible.

AMAS' review of the charges for 10 studies identified \$48,942 in misdirected laboratory charges, \$22,843 in misdirected Infusion Service charges, and \$13,607 (***Exhibit C-1***) in device expenses for infusion pumps that were inappropriately posted to the subject's account for billing to third party payers. We also identified charges totaling \$15,229 (***Exhibit C-2***) that should have been charged to an insurance account but were erroneously charged to a study bulk account. Charges had not been submitted for six subjects' study procedures included in the sample (***Exhibit C-3***).

We noted that seven of the 10 studies sampled contained at least one misdirected laboratory charge. Misdirected laboratory charges were caused by incorrect test orders being entered into Epic by research staff, and/or a delay in the implementation of an Epic programming change. Other charges inappropriately charged to a study bulk account would have been corrected earlier if the bulk account had been monitored regularly to ensure the validity of charges. Improved communication between the research unit and departments that provided study procedures could also have reduced the number of misdirected charges.

Since completion of audit fieldwork, a number of process improvements have been implemented. These improvements are reflected in management corrective actions and/or in footnotes.

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The following Management Corrective Actions have been agreed upon or implemented to resolve the issues identified in the report:

- Health Sciences management has convened a Clinical Research Billing Steering Committee (CRBSC) to provide management oversight over the research charge capture process. The Committee has hired an outside consultant to assist in clinical research charge capture and billing process redesign and implementation.
- The Epic Project Team has implemented in production the Beacon program that will ensure that research registration information is accurately transferred and received in the LIS for all outpatient charges with a research bill to bulk (RBB) order class.
- Epic training will educate research personnel on appropriate ordering procedures and on the type of information needs to be in Epic to facilitate accurate charge capture.
- The Health Sciences Research Compliance Program (RCP) will continue to provide training to study coordinators on the research process, and will continue to conduct research charge monitoring reviews.

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I. Background

Audit & Management Advisory Services (AMAS) has completed a review of selected clinical research billing processes as part of the approved audit plan for Fiscal Year 2009-10. This report summarizes the results of our review.

During the Fiscal Year 2009-10, UCSD had over 700 faculty members conducting clinical research that involved human subjects. There were approximately 3,500 active clinical trials being conducted during this time frame. Clinical trials may be funded by commercial sponsors, federal agencies or through the use of UCSD departmental funds. Clinical trial projects have both regulatory and financial implications to the University, and for that reason, project proposals are submitted to numerous review processes prior to approval.

The following study pre approval processes help to ensure each study receives appropriate evaluation and that a research account has been established.

Study Protocol Reviews

All research activity, including retrospective chart reviews, and the use of existing tissue and/or laboratory samples, requires Institutional Review Board (IRB) review and approval unless an exemption is granted. A research protocol developed by the study sponsor or the Principal Investigator (PI) is submitted to the IRB for initial approval, and ongoing oversight to ensure the ethical conduct of the trial and to mitigate the risks associated with research protocols involving human subjects.

Study proposals for commercially sponsored clinical trials are routed through the Office of Clinical Trial Administration (OCTA) which administers the contract and budget negotiation process. Similarly, study proposals for federally sponsored clinical trials are routed through the Office of Contract and Grant Administration (OCGA). The OCTA and the OCGA work with the Conflict of Interest office and the IRB to review documents submitted and track approval.

In accordance with UCOP Operating Requirement, No. 95-5, "Requirements for Administration of Agreements with Private Sponsors for Drug and Device Testing Using Human Subjects," all agreements between the University and the sponsor must make explicit that the sponsor assumes responsibility for reimbursing the University for the reasonable cost of medical treatment for injuries directly resulting from participation in the study. The UCSD Research Compliance Program (RCP) completes a study risk assessment, concurrently with the IRB proposal review, to ensure that financial accountability for potential costs associated with potential serious adverse events has been defined.

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Bulk Account Application

The PI (or his/her designee) is required to apply for an institutional bulk account if any UCSD Medical Center (MC) ancillary/clinical or professional services are utilized during the study. Research services are billed at the applicable research rates. A bulk account application is used to obtain approved research rates for laboratory and radiology services, and a Departmental Research Agreement (DRA) is used to request technical¹ and professional research rates from all other departments that provide study related services. Research rates for a number of outpatient visits are standardized and entered into the MC Charge Description Master (CDM). Case research rates (technical fees) are obtained from Medical Center Financial Services for inpatient admissions or outpatient procedures. Professional fees research rates are entered into a specific dictionary in the Medical Group (MG) billing system, GE-IDXBAR, based on the rates approved on DRAs and bulk applications.

Documentation supporting each clinical trial should identify procedures that will be performed specific to research versus for standard of care treatment. Charges for research related services are billed to the study. However, there may also be standard of care services provided to the study subject that are billable to the subject's insurance. The PI currently determines which procedures will be considered standard of care.

The correct application of the following post approval processes are critical for accurate charge capture and billing to occur.

Subject Registration

Once the IRB approval is obtained and other project support documents such as a sponsor contract and DRAs are finalized, a bulk account is established for study related activities. Subjects enrolled in a study must be registered to the study bulk account, which is maintained in the MC Financial Management System (FMS). A registration is created with a research payer code (type K or P07/P08). At the close of the study, the PI contacts Patient Financial Services (PFS) and Patient Access to close the bulk account and associated subject registrations to avoid an incorrect selection of the subject's research registration for any future appointments or charges.

Charge Entry and Scheduling

Charge entry is initiated by the research unit by creating an order for a study related service that is approved by the study PI. The ordered service is then scheduled in GE-IDX or another scheduling system. When the subject arrives for the scheduled service, department staff link the service and any related charges to either the research bulk account or the subject's regular account by selecting the correct registration.

MC Imaging Services schedules all services in the radiology information system, Agfa. Orders can be placed electronically through Epic or on a paper form. Research staff use

¹ As of October 2010, DRA's are not required for hospital technical fees.

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the “Research Bill to Bulk” (RBB) order class and add comments when ordering in Epic indicating the patient is on a research study. Imaging Services check-in staff then select the appropriate registration based on the Epic order class and comments made at time of ordering. ***Exhibit A*** provides additional details about the Imaging Services scheduling and patient intake process flow.

Bulk Account Review

The PI or the study coordinator is responsible for completing a monthly reconciliation of study bulk account charges with expected research related services. The purpose of this review is to verify that only study related charges are allocated to the bulk account, and to identify any study charges that have not been posted to the bulk account. If any charge errors are identified during the review, the study coordinator or research account specialist contacts PFS and/or MG staff to request charge corrections. Laboratory or radiology charge correction requests are sent directly to the respective department for processing.

MC and MG managements are responsible for the design and maintenance of core charge capture and billing systems and related processes for all types of patient related services including research. Individual service departments such as Cardiology, Imaging Services and the Clinical Laboratories may also implement procedures within their areas to facilitate ordering, scheduling and charge entry processes.

The RCP assists MC and MG managements with promoting institutional compliance by providing staff training, participating in research billing system discussions, and monitoring research charges. For example, the RCP has performed a review of certain research charges associated with investigative device studies to ensure appropriate charge capture and billing occurred.

The RCP general research helpline is a valuable resource for research coordinators and research billing staff to obtain answers to research related questions and related MC processes. The RCP Director also convenes the Clinical Research Process Action Team (PAT), a group of UCSD staff that help to manage, or that utilize MC and MG systems to complete, research studies. The PAT provides a forum for communicating and resolving issues. In addition, RCP maintains an Intranet site that provides a number of University or external agency references that are relevant to the conduct of clinical trials at UCSD.

II. Audit Objective, Scope, and Procedures

The objective of our review was to evaluate clinical trial charge entry and capture processes from the point of order to the allocation of charges to research bulk accounts or other patient accounts to determine whether research related services were directed to appropriate accounts in accordance with the study protocols, informed consents and/or related contracts.

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In order to achieve our objectives we completed the following:

- Obtained an understanding of the clinical trial charge entry and capture process by conducting interviews with the RCP Director and administrative staff for Imaging Services, Moores Cancer Center (MCC) Clinical Trials Office (CTO) and the Infusion Center;
- Prepared process flowcharts for Imaging Services scheduling and patient intake processes (*Exhibit A*), and the MCC lab order entry process (*Exhibit B*);
- Evaluated test ordering and charge capture processes, and identified process controls and deficiencies;
- Selected a judgmental sample of 10 studies to determine whether clinical trial related services were appropriately charged to the related insurance accounts or the research bulk account.
- Determined the cause of identified misdirected charges.

The audit scope was limited to the period August 2009 to May 2010. Consequently, all changes to processes or charges implemented after May 2010 are not addressed in this report.

Audit findings associated with physician professional services for the studies included in the audit sample were reported in the audit report for *Medical Group Clinical Research Billing Review*, AMAS Project # 2010-25, which was completed concurrently with this project.

Sample Set Selection

A judgmental sample of 10 studies performed throughout the campus was selected for this review. The December 2009 and January 2010 PFS and MG bulk account statements were accessed from InfoPac². The population was confined to studies that had both MC and MG charges for those months.

Up to 10 patients were randomly selected from each study. Detailed information for each study selected is presented in the table below.

IRB #	Bulk Account #	Abbreviated Study Title	SOM Department or Organized Research Unit	Total Subjects Enrolled	Subjects Included in Sample
081783	9922485	Torax	Surgery	21	10
090240	9933854	Bazhenova-Morab-009	Moores Cancer Center (MCC)	5	5
071340	9922428	Plaxe GOG	MCC	6	6
090502	9936212	Helsten – TDM	MCC	2	2
081093	9934795	Jameson-MF	MCC	4	4

² Infopac is a report repository within Patient Care Information System (PCIS)

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IRB #	Bulk Account #	Abbreviated Study Title	SOM Department or Organized Research Unit	Total Subjects Enrolled	Subjects Included in Sample
		TG101348-0			
051037	9930934	MUST Trial	Ophthalmology	10	10
090531	9935008	Glaxo ADC112355	Internal Medicine	10	10
071588	9934159	MD Wallace	Anesthesiology	9	9
070885	9928482	Optima	Psychology	8	8
060635	9928979	NTM Study A	Medicine	74	10

III. Conclusion

Based on our audit procedures, we concluded that charges for research related services were not consistently directed to the appropriate patient account as defined by study protocols, informed consents and/or sponsor contracts. Several different manual or electronic test and procedure order processes were used. The complexity of certain aspects of the research charge capture process required the participation of a number of staff in various MC administrative and clinical service departments.

The current research charge capture and billing infrastructure does not support effective communication of study information and requires coordination and collaboration between departments that generally do not work together. Research processes and systems should be examined and analyzed to maximize integrity in conducting research and to establish accountability. Processes should be designed to manage and coordinate information to ensure that accountability for billing accuracy is clearly defined, and that research billing errors are prevented whenever possible.

AMAS' review of the charges for 10 studies identified \$48,942 in misdirected laboratory charges, \$22,843 in misdirected Infusion Service charges, and \$13,607 (*Exhibit C-1*) in device expenses for infusion pumps that were inappropriately posted to the subject's account for billing to third party payers. We also identified charges totaling \$15,229 (*Exhibit C-2*) that should have been charged to an insurance account but were erroneously charged to a study bulk account. Charges had not been submitted for six subjects' study procedures included in the sample (*Exhibit C-3*).

We noted that seven of the 10 studies sampled contained at least one misdirected laboratory charge. Misdirected laboratory charges were caused by incorrect test orders being entered into Epic by research staff, and/or a delay in the implementation of an Epic programming change. Other charges inappropriately charged to a study bulk account would have been corrected earlier if the bulk account had been monitored regularly to ensure the validity of charges. Improved communication between the research unit and departments that provided study procedures could also have reduced the number of misdirected charges.

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Since completion of audit fieldwork, a number of process improvements have been implemented. These improvements are reflected in management corrective actions and/or in footnotes.

Opportunities for process and system improvements are discussed in detail in the remainder of this report.

IV. Observations and Management Corrective Actions

A. Research Charge Capture Process Oversight

The various system weaknesses identified during this review were indicative of complex processes that would benefit from focused management oversight.

Analysis of sample research charges identified a variety of issues that resulted in charges being misdirected to the wrong account. System weaknesses identified included failure to periodically communicate how study procedures should be charged to the research unit, computer system programming or change control issues, incorrect test order processes or the absence of order documents. Selected studies appeared to have a unique charge capture protocol that was necessary to ensure that charges were directed to the correct account, which was indicative that processes may be ineffective and sometimes not well understood by research and department staff.

RCP has collaborated with MC and MG to re-engineer some aspects of research charge capture processes, and to improve research bulk account reports to assist with the early detection of charge errors. In the near future, UCSD plans to implement Velos, which is a clinical research management application designed to support study administration and clinical data management. Consistent cross functional management oversight of clinical research management systems, charge capture and billing processes is needed to ensure that appropriate system and process solutions are identified and coordinated with key stakeholders. Establishing clear accountability for charge accuracy is necessary to assure that appropriate system changes are implemented.

Management Corrective Actions:

Health Sciences management has convened a Clinical Research Billing Steering Committee (CRBSC) co-chaired by the School of Medicine (SOM) Dean of Translational Medicine and the Chief Health Sciences Compliance and Privacy Officer. The charge to the Committee is to develop and implement a standardized process to conduct study related billing that is consistent with applicable Federal and State laws (inclusive of billing under Medicare's Clinical Trial Policy and Senate Bill 37), and

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University Policy for all UCSD Institutional Review Board (IRB) approved clinical trials conducted at UCSD.

The Committee has hired an outside consultant to assist in clinical research charge capture and billing process redesign and implementation. The outside consultant will also address alternative organizational structures to assure optimal coordination and communication among all offices involved in clinical research, and clear accountability for charge capture and billing.

B. Epic Laboratory Orders

Research related laboratory tests ordered in Epic were not correctly captured for billing purposes.

The Epic electronic medical record system has been implemented in the majority of UCSD outpatient clinics, including the MCC, which went live on the Epic Beacon application in April 2009. Because MCC patients are frequently provided the option of participating in a clinical trial, both standard of care and research related services associated with cancer clinical trials are ordered in Epic. When a laboratory order is processed through Epic, a charge is also created.

The research unit selection of an Epic order class determines the account to which the associated charge is routed (***Exhibit B***). The PI or the research staff member responsible for inputting orders into Epic is required to select from two order classes: normal, which routed the charge to the subject's insurance account, or "research bill to bulk" (RBB), which routes the associated charge to the study bulk account.

Four of the ten studies included in the audit test sample were cancer clinical trials that submitted laboratory orders through Epic. Of the \$48,942 total outpatient research laboratory charges that were misdirected to the insurance account (***Exhibit C-1***) for all clinical trials included in audit testing, charges totaling \$45,020 were associated with laboratory tests ordered in Epic for the four cancer trials in the sample. Of that amount, charges totaling \$30,367 (68%) were misdirected to the insurance account, even though the Epic orders were correctly entered by the research unit using the RBB order class. The remaining misdirected research related laboratory charges totaling \$14,653 (32%) were caused by the incorrect order class being selected by the PI or other cancer research unit staff when the Epic laboratory order was entered. The table below depicts the breakdown of the misdirected charges by study.

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IRB #	Dollar Amount of Misdirected Charges with a Correct Order	Dollar Amount of Misdirected Charges with an Incorrect Order
090240	\$9,666	\$10,771
081093	\$18,894	\$3,766
071340	\$104	\$51
090502	\$1,703	\$65
Total	\$30,367	\$14,653

To facilitate the appropriate application of laboratory charges to a subject's research or third party payer account, the Epic Project Team created a Beacon system program that would automatically select the study registration number from the Beacon research flow sheet for all RBB orders. The Beacon system research flow sheet included various study protocols and other information, and was updated by study coordinators. In fall 2009, MCC clinical laboratory staff were advised by the Epic Project Team that the program was active, and that RBB laboratory test orders could be released to the Laboratory Information System (LIS) without selecting a patient registration number to be appended to the order. However, the CTO continued to identify misdirected laboratory charges, and notified the RCP and the Epic Project Team in late 2009.

In April 2010, AMAS was advised by the CTO that outpatient research laboratory charges continued to be directed to the insurance account rather than the study bulk account. AMAS contacted Clinical Laboratory management, the RCP Director and the Epic Project Team to attempt to determine why the problem had not been resolved. During those conversations, the Epic Project Team determined that the Beacon program for routing RBB test orders had not been moved from the test system to production. Therefore, the Beacon system was not accessing the research flow sheet to obtain the study bulk account information for laboratory orders placed with the RBB order class. In addition, the LIS was designed to automatically select the first active registration number for subject, which was not linked to the study bulk account if a registration number was not selected when the order was submitted. As a result, RBB orders submitted through Beacon were being incorrectly billed to insurance.

We also noted that MCC staff understood that they were required to enter account information into the research flow sheet only for study subjects who received Infusion Center services. Therefore, that information was not available in the research profile for some MCC study subjects, and research discrepancies could have occurred even if the Epic-Beacon interface had functioned as designed.

The MCC clinical laboratory staff also released stat laboratory test orders from Epic to the LIS. When processing routine RBB orders, staff manually selected the subject registration number that was linked to a bulk account when accessioning the

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laboratory sample for processing. Therefore, routine RBB orders accessioned at the MCC clinical laboratory were billed correctly, provided that the correct subject registration information (linked to the study's bulk account) was selected by laboratory staff.

Management Corrective Actions:

1. CTO staff has submitted charge corrections for the errors identified in the four studies reviewed.
2. The Epic Project Team has implemented in production the Beacon program that will ensure that research registration information is accurately transferred and received in the LIS for all outpatient charges with a RBB order class. The Team will follow up to ensure that this program is operating effectively.
3. The Epic Project Team will produce a report to identify laboratory tests ordered in Epic with an RBB order class that do not have corresponding research subject information in the Beacon research profile to help prevent research test orders from being interfaced to the LIS without correct registration information
4. The RCP has requested that research orders for studies not conducted by the MCC not be ordered through Epic until system interface issues have been addressed.
5. The CRBSC will oversee the creation of an accountable office to ensure that research related charges are appropriately captured.
6. Epic training will include education on inclusion of necessary information in the MCC research flow sheet for accurate charge capture.

C. Research Bulk Account Review

Research bulk accounts were not monitored effectively to ensure charges billed were valid and complete.

The "Staff Handbook for Conducting Research and Clinical Trial Activities at the UCSD Medical Center" revised by the RCP in February 2011 specifies the charge monitoring responsibilities of the PI/designee in the clinical trial process. PI's are required to review and reconcile their research bulk account statements monthly. The review includes ensuring that charges billed to the bulk account relate to the study,

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and identifying study related charges that do not appear on the bulk statement. If study procedures do not appear on the bulk statement, the PI/designees are advised to inform PFS and/or the department that provided the service so that the department can follow up to determine why the charges were not posted. PI's may obtain daily, weekly or monthly MC bulk statements from InfoPac. Regular monitoring of the bulk accounts facilitates timely identification and correction of misdirected or missing charges.

In addition, research units should review statements received from PFS for any inpatient or outpatient charges that are billed to the study to identify any discrepancies.

During review of the ten studies sampled, it was observed that PI's or study coordinators did not regularly review bulk accounts for invalid charges and/or for missing study charges. Consistent review of the study procedure charges would have resulted in earlier detection and correction of errors identified during this review.

Management Corrective Actions:

1. In November 2009, the CTO established internal processes to ensure proper oversight of standard of care and research charge entry.
2. The CTO has taken steps to correct cancer trial misdirected charges identified during this review.
3. The RCP will continue efforts to educate study coordinators about the importance of reviewing bulk account statements for completeness on a regular basis to identify misdirected charges and billing errors.
4. The RCP will continue research charge monitoring to ensure the accuracy of clinical research charge capture and billing.

D. Beacon Charge Losses

Certain charges were misdirected during the transfer from Beacon to FMS.

AMAS identified one subject in study IRB#090502, for which an infusion service charge could not be traced to the study bulk account or to a third party payer account. AMAS discussed the missing charge with the Epic Project Team and Medical Center Information Services (Information Services).

During an initial evaluation into the missing charge, AMAS found that the charge had been released from the Beacon system; however, the applicable subject registration

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number, present in the Beacon research flow sheet, was not linked to the charge. Therefore, the charge was released without the appropriate account information. The absence of this information would typically route the charge to FMS edit report for Infusion Center management to review and correct. When AMAS did not locate the charge on SMSS038 reports, additional assistance was requested from Information Services.

On a daily basis, charges are released from Beacon for transfer to FMS. When the Beacon system was implemented, Information Services wrote a program to assign a "99BK..." patient number value to any charges for which a patient registration number or research bulk account number was not present or cannot be identified. Those charges should then be rejected by FMS and routed to applicable FMS rejection reports for further review and processing. However, Information Services determined that all charges assigned a "99BK..." value were being rejected by FMS upon transfer, and were then removed from the queue. Information Services identified 1,075 such charge records dating back to April 2009, which had accumulated in a suspense file.

All charges should be posted to the appropriate account on a timely basis to avoid processing delays. A subsequent analysis of the suspense file transactions described above was performed by the Director of Revenue Cycle Administration. This analysis revealed that 75% of the charge records did not link to an active research bulk account registration on the date of service. Further, this analysis identified that, for the records for which price data could be obtained, technical charges totaling \$61K at research rates, or \$198K at standard billing rates, had not been captured. The MCC CTO also reviewed the suspense file transactions, and indicated that charges totaling \$130K were for services ordered for federal cooperative group studies. Because the charges for federal cooperative group study services are typically directed to a third party payer account, bulk account registrations are not created for subjects enrolled in those studies.

Management Corrective Actions:

1. In May 2010, Information Services modified the FMS charge record value that was assigned when no patient/bulk number was present in the Beacon charge file. If charges transfer without appropriate registration information in the future, they will be rejected by FMS, and routed to applicable rejection reports for department review.
2. IS has provided an extract of the suspended charge records to the Pharmacy for review and correction.

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3. CTO has completed an analysis of the suspended charge file, which will be provided to the Director of Revenue Cycle Administration to facilitate charge posting.
4. The RCP has established general training for study coordinators includes all aspects of the bulk registration process.

E. Misdirected Charges – Research Unit

Some cancer trial charges were misdirected when the research unit placed an order incorrectly or did not transition to the bulk account on a timely basis.

The table below³ provides the total amount of misdirected charges for selected tests performed for the 10 sampled studies. The majority of the misdirected charges identified in the table occurred due to the selection of an incorrect Epic order class, or an incorrect account number when the test was ordered. The remaining charges were misdirected to a research bulk account used for prior study phases pending the establishment of a new account.

IRB #	Service Type	Dollar Amount	Charges posted to:	Cause
090240	Laboratory	\$10,771	Subject's third party payer account	Incorrect order placed by Research Unit
090240	Pulmonary	\$1,679	Subject's third party payer account	Incorrect order placed by Research Unit
090240	CT Scan	\$962	Subject's third party payer account	Incorrect order placed by Research Unit
071340	Laboratory	\$51	Subject's third party payer account	Incorrect order placed by Research Unit
090502	Pregnancy test	\$214	Subject's third party payer account	Incorrect order placed by Research Unit
090502	Laboratory	\$65	Subject's third party payer account	Incorrect order placed by Research Unit
081093	Laboratory	\$3,766	Subject's third party payer account	Incorrect order placed by Research Unit
081093	Laboratory	\$1,617	Incorrect bulk account	Research Unit transitioning to new bulk account
081093	Bone marrow	\$451	Incorrect bulk account	Research Unit transitioning to new bulk account

³ The misdirected charges in the table are a subset of Exhibits C1-C2, which include the total of misdirected charges to either insurance accounts or bulk accounts identified for all studies in the sample. The table references misdirected charges that resulted from research unit operations for four of the studies in the sample.

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Misdirected charges totaling \$19,576 could have been avoided if orders had been placed correctly or the research unit had established a new study bulk account in a timely manner.

Management Corrective Actions:

1. Study coordinator training programs established by the RCP will include ordering practices.
2. Epic training will provide guidance on research service ordering processes.

F. Infusion Center Charge Capture

Communication between the CTO and the Infusion Center coding and charge entry staff regarding split billing for services provided to MCC clinical trial subjects is critical to ensure that charges are allocated to the appropriate account.

Study subjects scheduled for Infusion Center visits sometimes received standard of care and research services during the same visit. When this occurred, Infusion Center coding and charge entry staff were required to split the charges between the third party payer and research accounts. In Beacon, only one account registration can be linked to each Infusion Center visit. As a result, the Infusion Center scheduling request requires that the third party payer account be selected when any portion of the charge for the visit should be billed as standard of care. Because both the research and third party payer account cannot be linked to a visit when both services are provided, additional care must be taken when charges are entered to ensure that they are directed to the appropriate account.

During the charge capture process, Infusion Center coding and charge entry staff review visit notes in Beacon to identify the charges to be billed, and add a “Bill to Bulk” (BTB) modifier to any charge to be directed to the research bulk account. Inadequate information regarding how visit charges should be allocated could cause some charges to be misdirected to the wrong account, resulting in additional work for the CTO, PFS and the MG to ensure that charge corrections are processed.

Management Corrective Actions:

1. In February 2010, Infusion Center and the CTO established a weekly process that requires the CTO to provide information to assist Infusion Center coding and charge entry staff with allocating services between standard of care and research.

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2. The CRBSC will oversee the implementation of changes to clinical research billing systems and processes to facilitate accurate charge allocation.

G. Order Documents

Procedure orders were not available to assist with evaluating misdirected research charges in some cases.

Infusion Center

Infusion charge errors on ***Exhibit C-1*** totaled \$22,843. However, because source documents were not available to serve as an audit trail, AMAS could not identify the cause of charge errors totaling \$15,549 of that amount.

The research unit contacted the Infusion Center scheduling staff when a study visit was needed and a follow-up or electronic scheduling request form was not required. Therefore, it was not possible to determine whether the misdirected charge was caused by the visit being incorrectly requested by the ordering department as a standard of care visit, or whether a scheduling error had occurred. Beginning in November 2009, Infusion Center scheduling staff required a clinical trials return visit form (CTI form) to be submitted when infusion services were ordered. The paper scheduling request form was stored in the scheduling unit. The availability of those orders assisted AMAS with determining how infusion services were requested by the research unit for charges in the sample that occurred after that date.

Bone Marrow Transplant

Bone marrow test charges for IRB#081093 totaling \$12,000⁴ (***Exhibit C-1***) were misdirected to the subjects' insurance accounts. Bone marrow tests were ordered using a printed procedure request form that was faxed to the scheduling staff by the study coordinator. The procedure was then scheduled in the Operating Room Scheduling Office System (ORSOS) and the GE-IDX scheduling system. However, the printed form was discarded one month after the order was placed. Therefore, AMAS was not able to determine whether charges were misdirected due to an incorrect order or a scheduling error.

Medical Center Policy (MCP) 320.2h defines a seven year record retention period for all documents, including orders that become part of the medical record. Compliance

⁴ While the Research Project Manager indicated to AMAS during a March 2010 meeting that all five of these bone marrow test charges were research related and should have been billed to study bulk account, the CTO performed a subsequent review and determined that three of the five charges were in fact standard of care and could be billed to third party payer accounts based on the study schedule and PI discussion on standard of care and research billable designation for identified research visits.

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with this record retention requirement will help to ensure that all required documents are available when needed to facilitate patient care planning and administrative processes.

Management Corrective Actions:

1. In May 2010, the Infusion Center replaced the paper CTI form with an electronic Infusion Center Appointment Request for existing patients.
2. MCC Clinic management will follow the existing record retention period defined in Medical Center Policy (MCP) 320.2h for printed bone marrow test and electronic infusion services orders.

H. Recharge Device Charges

For one study, improved coordination between the study coordinators, the surgical nurse or surgery billing staff and the pump nurse was needed.

Study IRB#071588 required that the study participant undergo surgery to implant a device. The device was provided free of charge by the sponsor. However, the study was repeatedly charged for the device in spite of several discussions between the study coordinator and the surgical charge nurse to advise that the device should not be charged.

The Surgery billing staff used a paper charge sheet completed by the Operating Room charge nurse to bill for the surgery. Unless the charge sheet specified that the device should not be billed, the study bulk account was charged for the device. To prevent the device from being incorrectly charged, the research unit could improve communication of the device billing requirements by adding comments in the ORSOS admitting notes when the procedure is scheduled.

In one instance, AMAS identified device charges billed to the study's account in the campus Integrated Financial Information System for one subject's September 2009 surgery costs. Although the study coordinator identified the erroneous device charges and requested that PFS process a charge correction in December 2009, the charge correction had not yet been processed when audit tests were performed in March 2010, which prompted the study coordinator to send a second notification to PFS that charge correction had not been processed.

Pump costs incurred for the patients while on this study were required to be billed to the research bulk account. Pump services were ordered by contacting the pump nurse who made a notation that the service should be billed to the bulk account on the encounter record that was reviewed by the Infusion Center billing staff when

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submitting charges. However, audit tests identified \$13,607 (***Exhibit C-1***) of study related pump charges that were charged to insurance accounts. Because the Infusion Center billing staff retained paper orders for six months and some charges reviewed were more than six months old, a paper trail was not available for \$6,386 of the total charges. Misdirected charges totaling \$1,717 were caused by the billing staff not identifying the “bill to bulk account” note in the encounter record, which resulted in the charge being charged to insurance accounts. The remaining \$5,504 consisted of pump charges for four patients for which the bill to bulk notation was not entered into the encounter record. The research protocol required that pump charges be split between the insurance account and the research bulk account for the last study visit. Each of the four encounters with misdirected charges were associated with the last study visit.

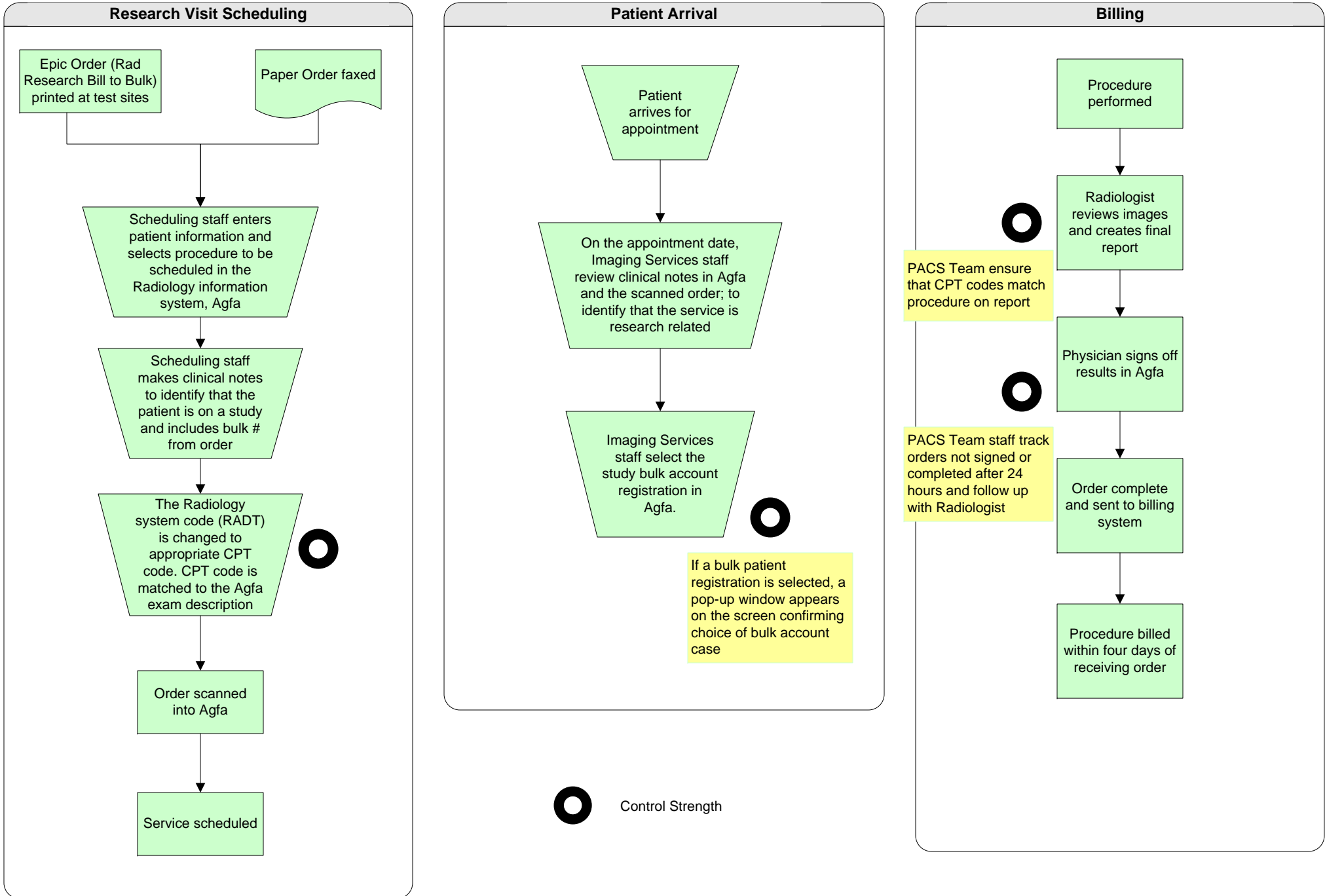
Consistent communication between the study coordinator, nursing, coding/charge capture, and billing staff, and consistent monitoring of study charges would likely improve the accuracy of billing for this type of clinical study.

Management Corrective Actions:

1. The study coordinator for IRB#071588 will clarify split billing visits to the pump nurse for future visits.
2. The Operating Room Business Office (ORBS) has been made aware of the device billing agreement for IRB#071588 which should lead to improved communications between the two parties about billing requirements. The study coordinator will communicate device billing conditions in advance to ORBS for any future device studies.
3. The research unit will advise the scheduling staff to add billing comments in the ORSOS scheduling system for the surgery.
4. A charge correction for device charges billed to IRB#071588 was ultimately processed after the second notification was sent.
5. RCP research charge monitoring reviews will include evaluation of investigational device charge capture and billing.

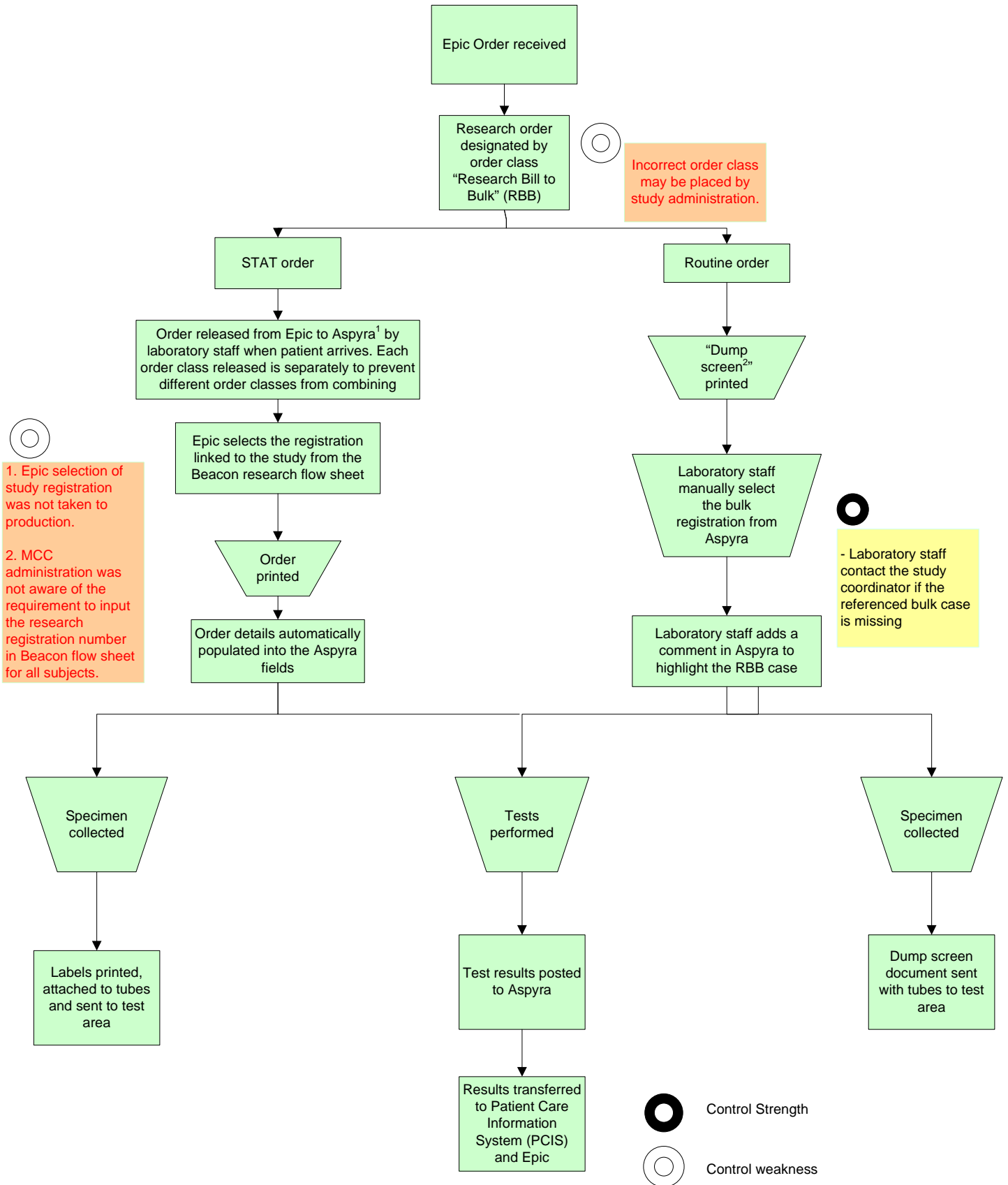
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EXHIBIT A – Imaging Services Study Procedure Billing Process



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EXHIBIT B - Moores Cancer Center Laboratory Epic Study Order Processing



1 Laboratory Information system
2 This is the EPIC screen for subject displaying research order

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Exhibit C1 - Chart of Exceptions by Study

IRB#	Study Name	Patient Initials	Study charges incorrectly billed to insurance/third party providers (technical fees only)							
			Labs	Infusion	Pulmonary	Bone Marrow	Surgery	Pump	ECG	Pregnancy Test
090240	MORAB	SC	\$ 1,807.00	\$ 4,662.00	\$ 1,366.00	\$ -	\$ -	\$ -	\$ -	\$ -
090240	MORAB	SR	\$ 5,625.00	\$ 8,643.00	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
090240	MORAB	CB	\$ 6,275.00	\$ 5,502.00	\$ 313.00	\$ -	\$ -	\$ -	\$ -	\$ -
090240	MORAB	BA	\$ 4,818.00	\$ 480.00	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
090240	MORAB	ML	\$ 1,912.00	\$ 3,332.00	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
<i>Total N2</i>			\$ 20,437.00	\$ 22,619.00	\$ 1,679.00	\$ -	\$ -	\$ -	\$ -	\$ -
081093	TargeGen	MS	\$ 5,578.00	\$ -	\$ -	\$ 1,298.00	\$ -	\$ -	\$ -	\$ -
081093	TargeGen	MA	\$ 6,394.00	\$ -	\$ -	\$ 2,503.00	\$ -	\$ -	\$ -	\$ -
081093	TargeGen	BT	\$ 8,183.00	\$ -	\$ -	\$ 5,289.00	\$ -	\$ -	\$ -	\$ -
081093	TargeGen	FD	\$ 2,505.00	\$ -	\$ -	\$ 2,910.00	\$ -	\$ -	\$ -	\$ -
<i>Total N2</i>			\$ 22,660.00	\$ -	\$ -	\$ 12,000.00	\$ -	\$ -	\$ -	\$ -
071340	Plaxe GOG	TS	\$ 95.00	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
071340	Plaxe GOG	SN	\$ 9.00	\$ 224.00	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
071340	Plaxe GOG	CS	\$ 51.00	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
<i>Total N2</i>			\$ 155.00	\$ 224.00	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
051037	MUST Trial	BF	\$ 22.00	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
051037	MUST Trial	AV	\$ 102.00	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
051037	MUST Trial	HB	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
051037	MUST Trial	SJR	\$ 215.00	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
051037	MUST Trial	CBB	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 63.00
051037	MUST Trial	KM	\$ 45.00	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
051037	MUST Trial	DG	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
051037	MUST Trial	SE	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
051037	MUST Trial	BD	\$ 94.00	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
<i>Total</i>			\$ 478.00	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 63.00
071588	MDWallace	PG	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 5,010.00	\$ -	\$ -
071588	MDWallace	WO	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 3,093.00	\$ -	\$ -
071588	MDWallace	EC	\$ -	\$ -	\$ -	\$ -	\$ 40,613.00	\$ 1,376.00	\$ -	\$ -
071588	MDWallace	CC	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 1,376.00	\$ -	\$ -
071588	MDWallace	MN	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 1,376.00	\$ -	\$ -
071588	MDWallace	LM	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 1,376.00	\$ -	\$ -
<i>Total</i>			\$ -	\$ -	\$ -	\$ -	\$ 40,613.00	\$ 13,607.00	\$ -	\$ -

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Exhibit C1 - Chart of Exceptions by Study

IRB#	Study Name		Study charges incorrectly billed to insurance/third party providers (technical fees only)								
			Labs	Infusion	Pulmonary	Bone Marrow	Surgery	Pump	ECG	Pregnancy Test	
060635	NTM study	FJ	\$ 704.00	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	
<i>Total</i>			\$ 704.00	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	
081783	TORAX	WN	\$ 701.00	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	
081783	TORAX	JK	\$ 473.00	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	
081783	TORAX	CBC	\$ 496.00	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	
081783	TORAX	RA	\$ 433.00	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	
081783	TORAX	SD	\$ 637.00	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	
<i>Total</i>			\$ 2,740.00	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	
090502	Helsten	SL	\$ 844.00	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 302.00	\$ 214.00	
090502	Helsten	MM	\$ 924.00	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	
<i>Total ^{N2}</i>			\$ 1,768.00	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 302.00	\$ 214.00	
Grand Total			\$ 140,263.00	\$ 48,942.00	\$ 22,843.00	\$ 1,679.00	\$ 12,000.00	\$ 40,613.00	\$ 13,607.00	\$ 302.00	\$ 277.00

(N1)

N1 Surgery was correctly scheduled for study in ORSOS. Registration creates a study patient number for the surgery procedures. The charges do not post to the bulk account but instead are posted to the study's financial account in the campus Financial Link (FinLink) system. Billing staff link to the patient number provided by Registration. In this case, an incorrect patient number was provided by Registration leading to surgery being billed to insurance.

N2 Total relates to a MCC study. It was noted that the lab errors billed to insurance or third party providers for the four studies totalled \$45,020

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Exhibit C2- Chart of Exceptions by Study

IRB#	Study Name	Patient Initials	Charges billed incorrectly to the bulk account					Study charges billed to the wrong bulk account	
			Imaging	Labs	Surgery	Mispostings	Double billing	Labs	Bone Marrow
090240	MORAB	SR	\$ 962.00	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Total			\$ 962.00	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
081093	TargeGen	MS	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 1,396.00	\$ 451.00
081093	TargeGen	MA	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 221.00	\$ -
Total			\$ -	\$ -	\$ -	\$ -	\$ -	\$ 1,617.00	\$ 451.00
071588	MDWallace	PG	\$ -	\$ -	\$ -	\$ 164.00	\$ -	\$ -	\$ -
071588	MDWallace	EM	\$ -	\$ -	\$ -	\$ -	\$ 287.00	\$ -	\$ -
071588	MDWallace	WO	\$ -	\$ -	\$ -	\$ -	\$ 122.00	\$ -	\$ -
071588	MDWallace	CC	\$ -	\$ -	\$ -	\$ -	\$ 164.00	\$ -	\$ -
071588	MDWallace	DK	\$ -	\$ -	\$ -	\$ 50.00	\$ -	\$ -	\$ -
071588	MDWallace	MN	\$ -	\$ -	\$ -	(N1)	\$ -	\$ -	\$ -
Total			\$ -	\$ -	\$ -	\$ 214.00	\$ 573.00	\$ -	\$ -
060635	NTM study	FJ	\$ -	\$ 127.00	\$ -	\$ -	\$ -	\$ -	\$ -
Total			\$ -	\$ 127.00	\$ -	\$ -	\$ -	\$ -	\$ -
090502	Helsten	MM	\$ -	\$ 48.00	\$ -	\$ -	\$ -	\$ -	\$ -
Total			\$ -	\$ 48.00	\$ -	\$ -	\$ -	\$ -	\$ -
051037	MUST Trial	DG						\$ 11.74	
Total			\$ -	\$ -	\$ -	\$ -	\$ -	\$ 11.74	\$ -
081783	TORAX	LG	\$ -	\$ -	\$ -	\$ 69.61	\$ -	\$ -	\$ -
081783	TORAX	VP	\$ -	\$ -	\$ -	\$ 125.00	\$ -	\$ -	\$ -
081783	TORAX	RA	\$ -	\$ -	\$ -	\$ 407.00	\$ -	\$ -	\$ -
081783	TORAX	DM	\$ -	\$ -	\$ 10,672.00	\$ -	\$ -	\$ -	\$ -
Total			\$ -	\$ -	\$ 10,672.00	\$ 601.61	\$ -	\$ -	\$ -
Grand Total		\$ 15,229.35	\$ 962.00	\$ 127.00	\$ 10,672.00	\$ 815.61	\$ 573.00	\$ 1,628.74	\$ 451.00

(N2)

(N3)

N1 Patient was incorrectly charged for surgery device totalling \$10,696 to study index. There is also a missing charge for the surgery that needs to be charged to the bulk account at the research rate. Study coordinator requested correction in December from PFS.

N2 Biller bills to the patient number provided by registration. In this case, the patient number linked to the bulk case was provided by Registration for billing leading to charges being posted at the normal rate to the bulk account. Charges did not post at bulk rates as only outpatient visits have research rates uploaded in CDM - not surgery (which are charged to study index at case rates).

N3 Infusion Center biller incorrectly billed for the same service twice

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Exhibit C3 - Chart of Exceptions by Study

IRB#	Study Name	Patient Initials	Date(s) of service	Missing Charges			Notes
				Imaging	Lab	Infusion	
051037	MUST Trial	KM	3/29/2007		X		Possibly charged to insurance. Subject billing detail unavailable in PCIS for date of service as older account information was purged
070885	OPTIMA	HV	10/16/2008; 4/16/2009	X			Request not coded or billed out. PACS controls to review incomplete orders were implemented after date of service
070885	OPTIMA	SD	3/17/2009	X			Request not coded or billed out. PACS controls to review incomplete orders were implemented after date of service
090502	Helsten	MM	2/10/2010			X	System error. Refer to Finding D for further details