REVIEW OF HEALTH SCIENCE CENTER CANCER RESEARCH & TREATMENT CENTER OPERATION

THE UNIVERSITY OF NEW MEXICO

Report 2013-05
February 13, 2014

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ABBREVIATIONS

CC	Health Science Center Cancer Research and Treatment Center
CEO	Chief Executive Officer
FYE	Fiscal Year End
HIPAA	Health Insurance Portability and Accountability Act
HSC	Health Sciences Center
Internal Audit	University of New Mexico Internal Audit Department
IRB	Institutional Review Board
MOA	Memorandum of Agreement
MRO	Medical Records Office
NCI	National Cancer Institute
OIG	Office of Inspector General
PHI	Protected Health Information
POC	Performance Oversight Committee
SCI	State Coverage Insurance
SOM	School of Medicine
SRMC	Sandoval Regional Medical Center
SRS	Safety and Risk Services
UNMMG	University of New Mexico Medical Group
UNM	The University of New Mexico
UNMH	University of New Mexico Hospital
UPL	Upper Payment Limit

Financial Summary (in millions)

	FY 12	***FY 13***
Revenues	***$69.9***	***$65.8***
Expenses	***$69.5***	***$65.4***

Total FY 2013 Patients

In-State	***13,392***
Out-of-State	***299***
Total Patients	***13,691***

The Cancer Center provided Uncompensated Care in the amount of $4.5 million and $6.8 million in FY 12 and FY 13, respectively.

The Cancer Center is in compliance with requirements of HIPAA to protect privacy and confidentiality of patient data.

EXECUTIVE SUMMARY

Historically, the Health Science Center Cancer Research and Treatment Center (CC) was mandated by the New Mexico State Legislature as a component of the University of New Mexico School of Medicine (SOM) in 1971. The CC manages and directs: a large ambulatory ("out-patient") cancer diagnosis and clinical treatment program in concert with UNM Hospital (UNMH), and its cancer clinics are "hospital-based;" a large academic, research, and educational operation under the SOM; and a statewide community outreach program. As a consequence, the CC has staff from UNM, UNMH, and the UNM Medical Group. Physicians and researchers that work within the CC clinical, research, and outreach programs have their primary appointments within various SOM Departments. As such, they have a direct report to their Department Chair and a secondary report to the Cancer Center Director/CEO.

Today, the CC is the only National Cancer Institute (NCI) – Designated Cancer Center in the state of New Mexico, and one of only 68 premier Cancer Centers nationwide which hold this designation. The first NCI designation was earned in 2005, and after a competitive renewal process, was re-designated in 2010 by the nation's leading cancer agency for another five years. The UNM Cancer Center treats more than 60 percent of New Mexican adults and virtually all of the state's children affected by cancer.

HIPAA COMPLIANCE

The federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA") protects the privacy and confidentiality of an individual's health information. Known as "protected health information" or "PHI", the health information generally cannot be used or disclosed unless the individual who is the subject of the PHI has given prior written authorization or permission.

Compliance with HIPAA is vast and includes various areas. This audit reviewed compliance with three main areas: HIPAA training, medical record storage and release (HIPAA Privacy- 2003 and Security Rule - 2005), and breach notification.

CREDENTIALING AND SANCTIONS TEST

The credentialing process was completed timely and sanctions checks are being performed on a continual basis.

Clinical Affairs serves as the credentialing and privileging hub for UNM Health Sciences Center (UNM HSC). They are responsible for credentialing and re-credentialing members of the Medical Staff and other health care professionals as outlined in the Medical Staff Bylaws and related documents.

Various federal agencies have "exclusion lists" that contain individuals or businesses that are prohibited from doing business with the federal government. The persons and entities on each exclusion list are included on those lists because they broke the law. Offenses include healthcare fraud, certain drug offenses, or accusations of terrorism. Because UNMH receives money from the government, they are prohibited from hiring or contracting with excluded parties. For that reason, sanction checks are performed upon initial hire and on a continual basis.

DRUG INVENTORY AND RECONCILIATION

The prescription reconciliation process of the Cancer Center is considered "best practice" by the UNM HSC and has won several commendations and national recognitions by healthcare accrediting agencies (TJC, ASCO Quality Initiative, American College of Surgeons Commission on Cancer).

Prior to August 2009, the CC operated two infusion clinics, one was located at UNM Hospitals and the other was located at Lovelace Medical Center. In August 2009, the CC moved from UNMH to its current location at Camino de Salud. As a mutual decision between the CC and UNMH, the Adult Infusion Suite operates as a hospital based clinic. As a result, certain operating and financial responsibilities are designated to UNMH employees. One of the responsibilities delegated to UNMH employees is the inventory reconciliation process for high dollar drugs and the

The UNM CC clinical trials function (The Cancer Center Clinical Research Office) is reviewed and also audited annually by the NCI and many national accrediting agencies, and has been regularly evaluated as "excellent to outstanding."

reconciliation from dispensed drugs to billed charges for those high dollar drugs.

The drug reconciliation process is a unique process throughout the UNM Health System. This process, led by the UNM CC Chief Medical Officer, has been a collaborative effort between the CC pharmacy, UNMH revenue initiatives department, and CC billing department. It is the only location that currently uses this process and has evolved over the past three years.

CLINICAL TRIALS

Clinical trials are studies that evaluate the effectiveness of new drugs or treatment strategies. The development of more effective cancer treatments requires that new and innovative therapies be evaluated with cancer patients. Each clinical trial is designed to find new or better ways to treat cancer patients. In oncology, clinical trials are especially important because, in the absence of high cure rates, nearly all therapeutic approaches are developmental in nature.

There are three stages of a clinical trial: identify and obtain approval for clinical trial, open the trial, and close the trial. The UNM CC maintains a menu annually of nearly 300 cancer clinical trials, in order to provide access to new therapies and diagnostics for its patients.

BIOHAZARDOUS MATERIAL

With regard to tracking and disposal of chemicals, the Safety and Risk Services Department (SRS) is charged with oversight. Until November of 2013, SRS was also responsible for bio hazardous materials.

For FY13, the CC was not billed for any bio hazardous waste removal. They were billed $61,181.89 for Chemical/Infectious waste removal; that amount represented 6.7% of the total cost of Chemical/Infectious waste removal University wide.

CONCLUSION

The University of New Mexico CC is a Research and Treatment (Clinical) operation of the University of New Mexico School of Medicine (SOM). The CC clinical operations (multidisciplinary clinics, medical oncology/pharmacy/infusion, outpatient surgery, and radiation oncology) are all "hospital-based" and these clinical operations are integrated with and jointly managed by UNMH. Our review indicated that the CC has adequate internal controls in place for effective and efficient administration and to ensure compliance with laws, rules, regulations and agreements applicable to the cancer center.

Key Recommendations

1. Required Training (HIPAA and University wide courses) – The Director/Chief Executive Officer (CEO) of the UNM Cancer Center should work with the Cancer Center Human Resources Department and with the SOM Department Chairs (who hold primary responsibility for faculty) to ensure that all faculty and staff take the University's required training and HIPAA training courses.
2. Prescription Drug Reconciliation Policy and Procedures – The Director of Pharmacy should establish written policies and procedures regarding the specifics of the drug reconciliation process, to include what drugs will be reconciled and how often the top drug list will be reviewed.
3. Reconciliation of Prescriptions Administered to Billed – The Director of Pharmacy should ensure that the reconciliation process includes reconciling the list that the pharmacy generates for drugs administered to the inventory listing and billing report.

INTRODUCTION

BACKGROUND

Historically, the Health Science Center Cancer Research and Treatment Center (CC) was mandated by the NM State Legislature as a component of the UNM School of Medicine (SOM) in 1971. The CC manages and directs a large ambulatory ("out-patient") cancer diagnosis and clinical treatment program in concert with UNM Hospital (UNMH) and its cancer clinics are "hospital-based;" a large academic, research, and educational operation under the SOM; and a statewide community outreach program. As a consequence, the CC has staff from UNM, UNMH, and the UNM Medical Group. Physicians and researchers that work within the CC clinical, research, and outreach programs have their primary appointments within various SOM Departments. As such, they have a direct report to their Department Chair and a secondary report to the Cancer Center Director/CEO.

Today the CC is the only National Cancer Institute (NCI) – Designated Cancer Center in the state of New Mexico, one of only 68 premier Cancer Centers nationwide which hold this designation. The first NCI designation was earned in 2005, and after a competitive renewal process, was re-designated in 2010 by the nation's leading cancer agency for another five years. The UNM Cancer Center treats more than 60 percent of New Mexican adults and virtually all of the state's children affected by cancer.

The figure below provides the New Mexico County of residence of all patients treated at UNM Cancer Center in FY13:

	92
Out of State	299
Total	13,691

PATIENTS BY COUNTY FY 2013

Source: Cancer Center Administration

Cancer Center Mission

To ensure that all New Mexicans have access to world-class cancer care and benefit from advances in cancer research, the University of New Mexico Cancer Center will provide outstanding cancer diagnosis and treatment, conduct world-class research to discover the causes and the cures for cancer, educate the next generation of cancer healthcare professionals, and overcome the significant cancer health disparities in the Southwest through community-based outreach programs.

Accomplishments

Below is a list of CC Clinical Accomplishments:

- New Mexico's official Cancer Center and only NCI designated Cancer Center
  - Consortium: UNM; Los Alamos & Sandia National Laboratories; LRRI
- State's largest team of cancer specialists
  - 102 Oncology Trained M.D. Physicians
  - 136 research program members and cancer scientists (MD / PhD)
  - 448 clinical staff (Nurses, Pharmacists, Lab)
- State's only comprehensive cancer program: fully integrated cancer care (Medical, Surgical, Radiation, GYN, Pediatric; Palliative and Supportive Care)
- Caring for greater than 55% of adults and greater than 98% of children with cancer in NM
  - 44% of Patients from outside of Bernalillo County
  - 52% of patients: Racial/Ethnic Minorities

Below is a list of CC Quality/Research Accomplishments:

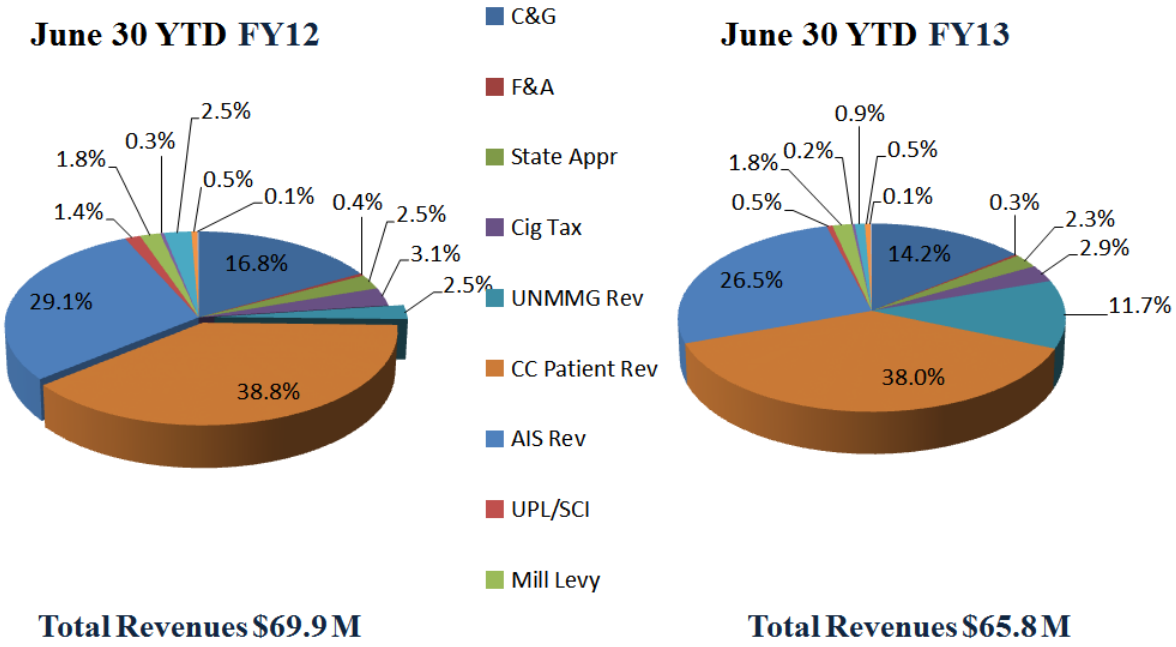
- Commendations for high quality care:
  - The Joint Commission: 2 "Best in Practice" Commendations (Radiation Oncology / Pharmacy & Infusion)
  - American College of Surgeons Commission on Cancer: Highest Commendation
  - American Society of Clinical Oncology: Outstanding Commendation

Revenues

The CC revenues are derived from: State Appropriations, shared receipts from the UNMMG, UNMH funding, CC Patient Revenues, Other Outpatient Services (Upper Payment Limit, State Coverage Insurance), Grant & Contract Revenue, F&A Allocations, Sales and Services, Cigarette Tax Revenues, and Other Revenues/Gifts. The pie charts below present revenue generated at the CC by category for FY12 and FY13.

Total Revenue

Period ending June 30, 2013



Source: Cancer Center Administration

C & G Revenue – Revenue associated with restricted and unrestricted contracts and grants.

F & A Revenue – Revenue from recovery of indirect costs (F & A) incurred by a contract or grant, also known as overhead return.

State Appropriations – Revenue received for current operations made available to UNM by act of New Mexico Legislature on an annual basis. Funding may be for research, public service, or independent operations.

New Mexico Cigarette Tax – The state imposes an excise tax for the privilege of selling, giving or consuming cigarettes in New Mexico. The UNM Cancer Center receives .83% from the New Mexico Cigarette Tax.

UNM Medical Group – Clinical revenue primarily based on physician or provider efforts and collection through UNM Medical Group.

Cancer Center Patient Revenue – Cancer Center patient revenues posted from the global billings net income.

AIS Revenue - Cancer Center patient revenues from Clinical Adult Infusion Suite.

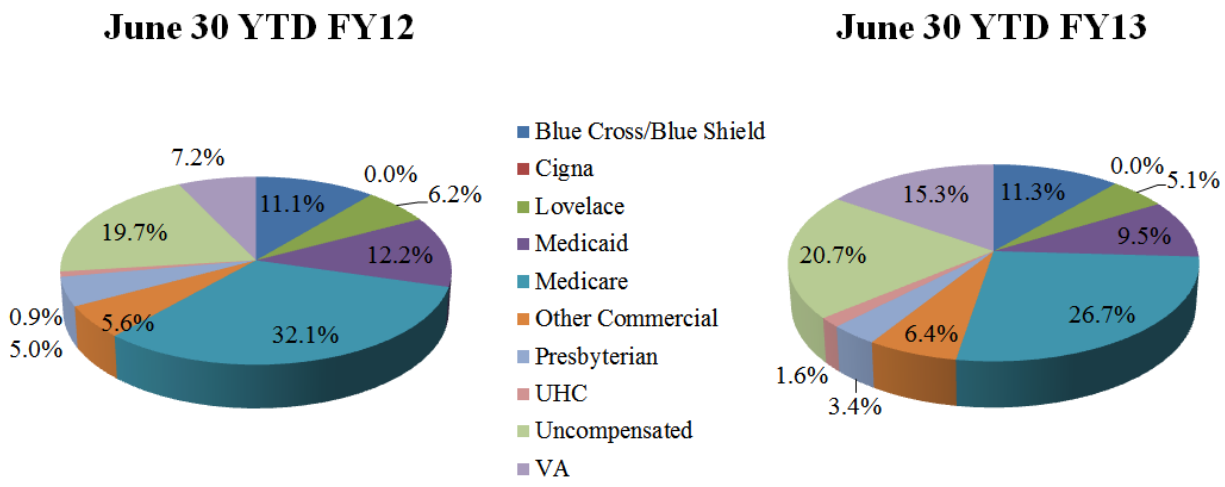
Mill Levy - Bernalillo County provides certain revenues to UNM Hospitals for its continued operation and maintenance. The revenues provided by Bernalillo County to UNM Hospitals are derived from the imposition of a mill levy approved by the electorate of Bernalillo County. The revenues generated by the mill levy will be utilized for operation and maintenance of UNM Hospitals. In exchange, UNM HSC provides care to indigent resident of Bernalillo County, contingent on availability of resources and funds.

Upper Payment Limit (UPL) - collections are calculated by the State of NM for Medicaid Services' claims processed through the State. The UPL is a federal limit placed on fee-for-service reimbursement of Medicaid providers. Specifically, the UPL is the maximum a given State Medicaid program may pay a type of provider in the aggregate statewide in Medicaid fee-for-service. State Medicaid programs cannot claim federal matching dollars for provider payments in excess of the applicable UPL.

State Coverage Insurance (SCI) – Patients can be enrolled in the coverage plan based on income levels. SCI offers affordable health care coverage to low-income working adults primarily through an employer-based system. The program is available for uninsured individuals aged 19 through 64 who do not have health insurance coverage and who are not eligible for other government programs.

Below is a chart of the areas that the CC receives payment from for its clinical services. Two of the largest payees have been Medicare and Medicaid. Veteran's Administration receipts doubled from one year to the next, and Blue Cross/Blue Shield has been the most consistent. One important note made was that uncompensated care increased by one percent. The Mill Levy and State Appropriations are important to helping fill the uncompensated care gap.

Payor Mix - Clinic Period ending June 30, 2013



Source: Cancer Center Administration

Uncompensated Care

Uncompensated care is an overall measure of clinical services provided for which no payment is expected to be received from the patient or insurer. It represents the uninsured and charity care provided by the facility and its providers. Uncompensated accounts are adjusted to bad debt, however are distinctly tracked for financial reporting purposes. A healthcare facility incurs bad debt when it cannot obtain reimbursement for care provided; this happens when patients are unable to pay their bills, do not apply for charity care, or are unwilling to pay their bills. Uncompensated care can be stated at billed charges or costs. UNM HSC states uncompensated care at cost.

Charity care (also called Indigent care) is the care that is provided to patients that have qualified for financial assistance programs. Qualification for the financial assistance programs is based on a patient making an application, verifying financial situation and meeting eligibility criteria. Financial assistance eligibility is based on the following:

- Residency Requirement – The patient must be living in New Mexico and demonstrate an intention to remain in the state.

- Financial Requirements – Patient's income is less than or equal to 300% of the federal poverty guidelines; and patient's assets need to be less than $15,000, excluding primary residence, vehicles and retirement funds.

Uninsured care is the care provided for patients that are classified as self-pay and do not or cannot pay some or all their bill. The write-off for the CC is recorded when the unpaid bill is sent to a collection agency. Under Medicare regulations, all services provided at a cost reporting hospital must be recorded at a uniform set of rates.

The CC, along with UNM HSC, provides the following financial programs to help offset uncompensated care:

- UNM Care Program Financial Assistance
- UNM Care Initiative (State Coverage Insurance)
- Out-of-County Medically Indigent Financial Assistance
- Self-Pay Discount Program
- Low Income Uninsured Patient Discount Eligibility
- Medical and Financial Assistance for Non-United States Citizens

The CC provides services to patients who do not have any healthcare insurance or do not qualify under any financial assistance programs. The CC does not pursue collection of amounts that qualify as charity care; however, the CC does pursue collection of the uninsured accounts through an extended payment plan or a discounted rate.

The CC provided $4.5 million in uncompensated care in FY 2012, and $6.8 million in FY 2013.

Expenses

Total operating expenses for FY 2012 and FY 2013 were $69.5 million and $65.4 million respectively; with 54% and 59% accounted for by salaries and benefits. The table below summarizes expense by major category for FY2012 and FY 2013.

	FY12	FY13
Faculty	$ 10,178,723	$ 9,836,236
Staff	20,135,209	21,588,757
Post Doc	514,689	471,027
Fringe Benefits	6,410,620	6,660,777
Infusion Drug Expense	14,320,951	13,087,393
Research Non-salary	7,851,411	7,078,659
Infusion Non-salary	4,271,529	631,755
Other Non-Salary	5,868,592	6,044,263
	$ 69,551,724	$ 65,398,867

Source: Cancer Center Administration

PURPOSE

The purpose of the audit was to gain and document an understanding of the CC operations and key practices. Our audit specifically reviewed the prescription drug reconciliation process and operational compliance with the following selected areas:

- HIPAA requirements;
- Administration of clinical trials;
- Credentialing and sanctions check practices; and
- UNM UAPPM over University-wide training.

SCOPE

The scope of the review was limited to compiling financial information on the CC operations and reviewing key practices at the CC for FYs 2012-2013. Key practices include payroll and hiring processes, credentialing processes, Memorandum of Agreement (MOA) management, bio-hazardous material control, prescription inventory control, the clinical trial process, and UNM required training.

PROCEDURES

Our review procedures included interviewing key personnel at the CC, Safety and Risk Services (SRS), and UNMH, reviewing internal documents, and performing analytical procedures on financial data, including billing and collections, expenses (payroll and other), and review of the pharmacy reconciliation.

OBSERVATIONS, RECOMMENDATIONS AND RESPONSES

HIPAA COMPLIANCE

The Federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA") protects the privacy and confidentiality of an individual's health information. Known as "protected health information" or "PHI", the health information generally cannot be used or disclosed unless the individual who is the subject of the PHI has given prior written authorization or permission.

Compliance with the Health Insurance Portability and Accountability Act (HIPAA) is vast and includes various areas. This audit reviewed compliance with three main areas: HIPAA training, medical record storage and release (HIPAA Privacy- 2003 and Security Rule - 2005), and breach notification.

The Joint Commission on Accreditation of Healthcare Organizations performs a "walk through" of the CC as part of their annual visit. HIPAA compliance is one of the areas they can be particularly interested in as part of their report. It is not disclosed what exactly they are looking at or for; however a review of the two most recent Joint Commission on Accreditation of Healthcare Organizations reports did not indicate any deficiencies related to HIPAA compliance.

The CC Ethics and Compliance Officer works with the HSC Compliance Office to ensure compliance in various areas, including HIPAA compliance. A monthly reporting process is followed; it includes submission of the UNM Cancer Center Compliance Report to HSC. The compliance report is a standard format provided by the HSC Compliance office. The areas reported on are:

- Current external compliance reviews
- Significant internal prevention/detection/correction projects
- Internal audit compliance reviews
- Education (training provided by compliance/coding office and training attended by office/staff)
- Significant changes/work efforts in the following areas this reporting period

The CC Ethics and Compliance Officer summarizes any compliance reporting issues on the report and forwards it to the Chief HSC Compliance Officer for his review. Any significant reporting areas are handled by the HSC Compliance office. Internal Audit reviewed the two most recent reports; neither report indicated any HIPAA compliance issues.

HIPPA Training

Pursuant to HIPAA, any entity which meets certain criteria is responsible for providing HIPAA training to its employees, trainees, agents, volunteers and contractors. This training includes the organization's HIPAA policies, privacy protections, violation procedures, computer protections and more. HIPAA does not specify the manner in which the training must be achieved.

UNM and UNMH have elected to provide HIPAA training online via Employee and Organizational Development training courses. Our audit included an analysis of the courses completed by all Cancer Center employees during 2012 and 2013 to determine the completion rate and therefore our success at compliance with required HIPAA training. The following HIPAA training courses were required for UNM HSC employees according to UNM HSC Privacy Office. These HIPAA training courses were basic courses required by UNM HSC for calendar year 2012 and 2013; other HIPAA training courses may need to be taken depending on the employee's job requirements and patient access level. Since the UNM Cancer Center is included with the UNM HSC employees, the same requirements must be adhered to for each calendar year.

The following HIPAA training courses were required in calendar year 2012:

1. HIPAA Training 2012 Privacy and Security - current employees and new hires
2. HIPAA Breach Notification 2012 - current employees and new hires
3. HIPAA Accounting and Disclosure 2012 - only for employees that required access to PowerChart

Internal Audit did not perform test work on the 2012 HIPAA Accounting and Disclosure training course. This training course was designated for CC employees that, as part of their job functions, needed access to PowerChart. There were a total of 68 CC employees that completed this training during calendar year 2012.

The following HIPAA training courses were required in calendar year 2013:

1. HIPAA Training 2013 Privacy and Security - only for new hires
2. HIPAA Breach Notification 2013 - only for new hires
3. HIPAA Accounting and Disclosure 2013 - current employees and new hires
4. HIPAA and HITECH 2013 - current employees who completed HIPAA Training 2012 Privacy and Security

Below are completion rates for 2012 and 2013 HIPAA training courses for the CC.

2012 and 2013 UNM Cancer Center Completion Rates for HIPAA training courses

2012

	Staff	Faculty
Training Privacy and Security - *Current employees and new hires*	77%	44%
Breach Notification - *Current employees and new hires*	61%	30%

2013

	Staff	Faculty
Training Privacy and Security - *Only for new hires*	98%	100%
Breach Notification - *Only for new hires*	98%	100%
Accounting and Disclosure - *Current employees and new hires*	95%	78%
HITECH - *Current employees who completed 2012 HIPAA Training Privacy and Security*	95%	67%

Note: Calendar year 2013 HIPAA training courses are still open for employees to complete until the 2014 HIPAA training courses are added. Per UNM HSC Privacy guidance, employees should take the HIPAA training courses for calendar year 2013 if they have not already taken the courses. The percentages above are calculated based on Learning Central data as of January 17, 2014.

University-Wide Training

While testing required HIPAA training, we also tested completion rates for the standard University-wide required training. The University of New Mexico requires mandatory training for employees in order to fulfill state and federal safety, risk, and employment law requirements. UNM employees, including faculty and staff, must take the required training annually through the University's Learning Central website. Directors and department heads have the discretion to exempt certain employees, such as on call and temporary employees, and employees that are less than .25 FTE; however, in making this decision, directors should consider the consequences in the event of a violation of legal and ethical practices.

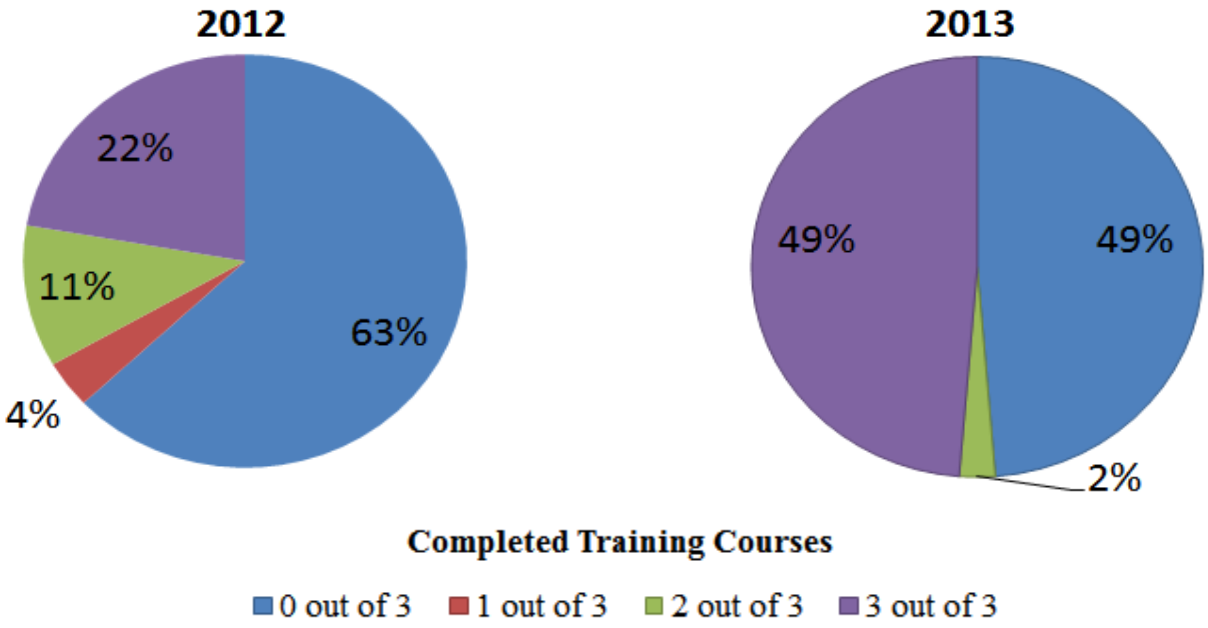
The required courses are:

- Preventing Sexual Harassment
- Basic Annual Safety Training
- Ethics: A Framework for Ethical Decision Making

Internal Audit conducted test work on required training data from Learning Central for calendar years 2012 and 2013 and found that faculty and staff did not adequately complete the required annual training.

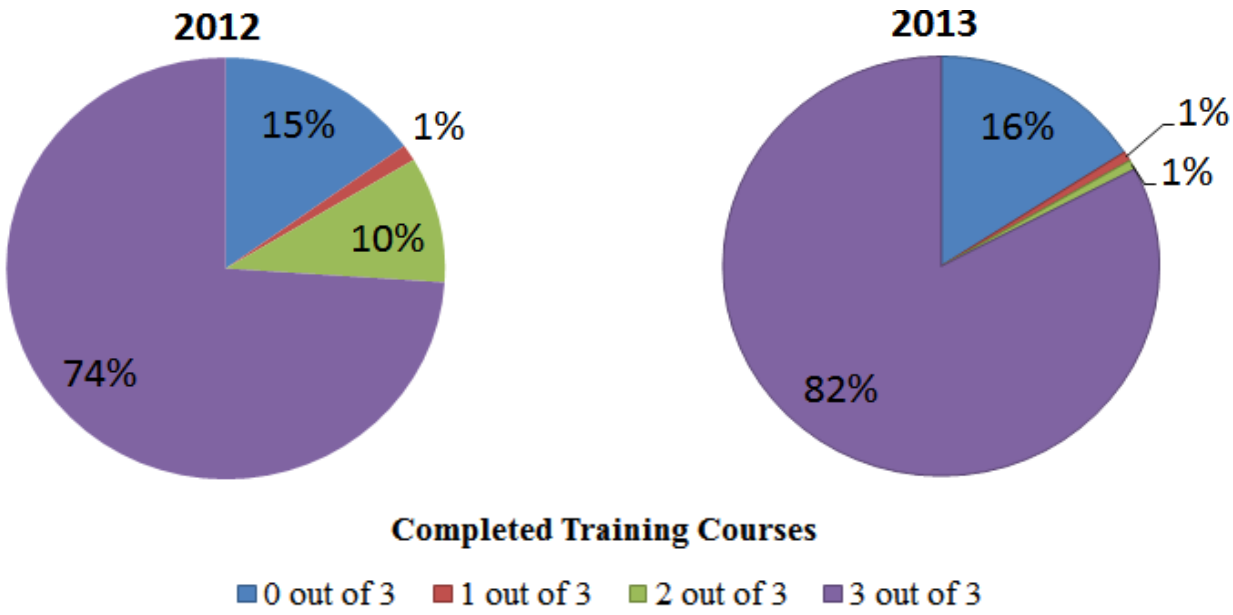
In calendar year 2012, 63% of CC faculty did not take any of the required training, and only 22% of faculty took all three required courses. In calendar year 2013, 49% of faculty did not take any of the required courses, with 49% completing all of the required training.

2012 and 2013 Required Training for UNM Cancer Center Faculty



In calendar year 2012, 15% of CC staff did not take any required training, and 74% of staff completed all three required courses. In calendar year 2013, 16% of CC staff did not take any required training, and 82% of staff completed all three required courses.

2012 and 2013 Required Training for UNM Cancer Center Staff



University departments are responsible for encouraging a healthy working environment that is ethical, promotes workplace safety, and respects employees' civil rights. Employee failure to complete required annual training could expose the University to legal liability or financial loss.

Recommendation 1

The Director/Chief Executive Officer of the UNM Cancer Center should work with the Cancer Center Human Resources Department and with the SOM Department Chairs (who hold primary responsibility for faculty) to ensure that all faculty and staff take the University's required training and HIPAA training courses.

Response from the Director/Chief Executive Officer of the UNM Cancer Center

Action Items: *The CC management team fully concurs with the recommendation for CC staff, over which we have primary authority and responsibility, and the corrective action plan for CC staff is provided below. Regarding SOM faculty who practice in the Cancer Center, please note that the primary authority and responsibility for these faculty resides with their SOM Department Chairs and Department/Division Administrators who must enforce and oversee such policies. The Director and CEO of the CC will work closely with the SOM Chairs to assure compliance with these expectations. However, during this audit and review of findings, it was discovered by the Administrator of the Division of Hematology/Oncology (including the Section of Radiation Oncology) in the SOM Department of Internal Medicine and our faculty providers, that beginning in August 2013, the UNM Learning Central online training and learning plans for these faculty were not properly loading for faculty to view and complete. Entire courses and*

required learning plans were missing for various providers. This systems issue, involving the identification of specific learning plans for each faculty member, loading these learning plans into Learning Central, and notification to faculty of the required completion dates is a systems issue outside of the CC which must be addressed. Due to these issues, we cannot currently determine which faculty have been able to complete their required training. We will continue to address this issue with the UNM entities responsible for the Learning Central Program.

Targeted Completion Date: *June 30, 2014 – Staff; December 31, 2014 - Faculty*

Assigned to:
For Staff: *UNM Cancer Center Human Resources Director, Front Line Managers and Supervisors for staff positions.*
For Faculty: *Relevant SOM Department Chairs, Division Administrators, and Cancer Center Director/CEO, working with UNM Learning Central.*

Corrective Action Planned:
UNM Cancer Center intends to address the recommendation for with the following actions.
Staff: *1) Cancer Center Human Resources will retrain managers and supervisors to ensure completion of required training is accurately tracked and noted on employee evaluations. 2) Cancer Center Human Resources will work with Learning Central to develop/obtain a detailed tracking report of required training courses by employee. Managers and Supervisors will receive a distribution of the status report monthly and will be contacted directly by Human Resources if outstanding training is not resolved within one month prior to completion deadline. Any employee missing the deadline will be required to complete the training immediately and will be subject to progressive discipline.*

Faculty: *UNM SOM Chairs/Administrators for faculty who practice in the Cancer Center (largely from the Departments of Internal Medicine, Surgery, OB/GYN and other Departments) will work with representatives from Learning Central to ensure faculty training plans are properly loaded for faculty. SOM Department Division Administrators will work closely with Chairs to audit and track completion; the Cancer Center Director and CEO will review completion of these learning plans with critical Department Chairs to assure completion.*

Medical Records

The HIPAA Security Rule establishes national standards to protect individuals' personal health information that is created, received, used, or maintained by a covered entity. The Security Rule requires appropriate administrative, physical and technical safeguards to ensure the confidentiality, integrity, and security of electronic protected health information.

Our audit reviewed how paper records at the CC were physically safeguarded and stored, and how patient information gathered electronically is safeguarded and stored. We also reviewed the medical record release request process.

The CC keeps electronic medical records; their system is "Power Chart." There are occasions when paper records are forwarded from other doctors with a referral. Those records are transferred to electronic copy and paper records are destroyed. Any paper records/films kept out of necessity are kept in the Medical Records Office (MRO). The MRO is locked and on the window there is a clear and large sign posted giving instructions to ring the bell for service and to not leave medical records unattended. A locked bin for information to be shredded is also onsite at the MRO, and a contracted service provider is responsible for shredding and disposing of any information in the bin.

Any request to obtain or view medical records is documented as per HIPAA requirements. Obtaining copies of medical records is administered by the Health Information Management department at HSC. Patients are directed to request medical records via a formal and centralized written request process administered at the HSC.

The CC utilizes three systems where patient information is kept:

- Mosaic – for scheduling and treatment/care plan information (chemo and radiation treatments)
- Power Chart – for patient medical record information
- Cerner – Patient medical record system housed at HSC

The CC does not maintain or house any servers onsite. They are maintained at the Health Sciences Library & Informatics Center and are all within the firewall at UNMH. All server management is documented via Memoranda of Understanding.

Doctors usually complete dictation in their assigned office or at home via a remote system access that requires unique and exclusive passwords to ensure patient medical information confidentiality. They also have a "work room" available to them that is usually not used for patient-specific dictation. It is generally a place to meet and confer about particular patient treatment/care; a place where doctors can brainstorm and collaborate.

The CC does not support or purchase I-pads, notebooks or handheld devices for use by the doctors. Laptops are encrypted, and Protected Health Information (PHI) is not stored on personal computers.

Security Information Breach

A breach is, generally, an impermissible use or disclosure under the Privacy Rule that compromises the security or privacy of the protected health information such that the use or disclosure poses a significant risk of financial, reputational, or other harm to the affected individual.

Following a breach of unsecured protected health information, covered entities must provide notification of the breach to affected individuals, the Secretary, and, in certain circumstances, to the media as follows:

•Individual Notice
Covered entities must notify affected individuals following the discovery of a breach of unsecured protected health information. Covered entities must provide this individual notice in written form by first-class mail, or alternatively, by e-mail if the affected individual has agreed to receive such notices electronically. If the covered entity has insufficient or out-of-date contact information for 10 or more individuals, the covered entity must provide substitute individual notice by either posting the notice on the home page of its web site or by providing the notice in major print or broadcast media where the affected individuals likely reside. If the covered entity has insufficient or out-of-date contact information for fewer than 10 individuals, the covered entity may provide substitute notice by an alternative form of written, telephone, or other means.

These individual notifications must be provided without unreasonable delay and in no case later than 60 days following the discovery of a breach and must include, to the extent possible, a description of the breach, a description of the types of information that were involved in the breach, the steps affected individuals should take to protect themselves from potential harm, a brief description of what the covered entity is doing to investigate the breach, mitigate the harm, and prevent further breaches, as well as contact information for the covered entity. Additionally, for substitute notice provided via web posting or major print or broadcast media, the notification must include a toll-free number for individuals to contact the covered entity to determine if their protected health information was involved in the breach.

•Media Notice
Covered entities that experience a breach affecting more than 500 residents of a State or jurisdiction are, in addition to notifying the affected individuals, required to provide notice to prominent media outlets serving the State or jurisdiction. Covered entities will likely provide this notification in the form of a press release to appropriate media outlets serving the affected area. Like individual notice, this media notification must be provided without unreasonable delay and in no case later than 60 days following the discovery of a breach and must include the same information required for the individual notice.

•Notice to the Secretary
In addition to notifying affected individuals and the media (where appropriate), covered entities must notify the Secretary of breaches of unsecured protected health information. Covered entities will notify the Secretary by visiting the HHS

> web site and filling out and electronically submitting a breach report form. If a breach affects 500 or more individuals, covered entities must notify the Secretary without unreasonable delay and in no case later than 60 days following a breach. If, however, a breach affects fewer than 500 individuals, the covered entity may notify the Secretary of such breaches on an annual basis. Reports of breaches affecting fewer than 500 individuals are due to the Secretary no later than 60 days after the end of the calendar year in which the breaches occurred.

Our audit included a review of recent security breaches at the CC, including how they were identified, researched and handled.

If a potential IT breach is ever reported it is directed to the HSC Incident Response Team. The most recent attack was in fall 2012; it was determined that the attack was only to gain access to the server to use it as a front for further attack, not to obtain specific data/information. Investigative efforts were led by the HSC Privacy Officer and the audit verified that the incident investigation and reporting were conducted in compliance with HIPAA. The investigation was timely and included required notifications to the potential 2,365 individuals, media and government agencies.

EXPENSE ANALYSIS: PAYROLL/HIRING AND OTHER EXPENSES

Payroll and Hiring

The CC has UNM, UNMH, UNMMG and contract employees. UNMH employees are in the Infusion Suite and the net effect of their cost is applied to the net margin of the Infusion Suite. UNM employees are paid as any other UNM employee. Contract employees are paid in accordance with their specific contract.

Prior to anyone being hired at the CC, a Position Request Form must be completed and submitted to the CC HR Manager for review/approval. Prior to making a request, the CC budget is reviewed for adequate funding source. Any position must be adequately supported by a specific purpose/need for the position. The Position Request Form requires CC signature approval at many levels prior to anyone being hired: Finance Department, Chief Financial Officer, Chief Medical Officer and CC Director/CEO. Once the Position Request Form is completed and approved by all required areas of the CC, it is forwarded to either the School of Medicine or the Medical Group, depending on the type of position being filled. If it is a UNMMG employee, the CC financial officer will have to communicate what index to charge the UNMMG employee salary and benefits to.

A detailed payroll invoice is sent once a month from the UNMMG to the CC. The invoice is in electronic and paper form and has various tabs that present the information in varying levels of detail. The total amount charged for the month is the initial cover page and the tabs in the electronic invoice drill down to employee list detail and then can be further broken down to specific employee detail.

The CC Finance department performs a monthly process to verify the accuracy of the invoice, as well as tie the total invoiced amount to Banner. The reconciliation includes a hash count of total UNMMG employees per invoice to the list of UNMMG employees on file with the CC. The total amount is reviewed at a high level for reasonableness. If the total appears lower or higher, then further analysis and research is done. Quarterly reports are completed, and close analysis of the payroll costs is completed.

The CC Finance department receives Banner reports every Monday, including the Operating and Budget reports. They are reviewed for accuracy and reconciliation to any invoices/support received. Payroll charges are checked against the Banner report.

Other Expenses

UNMMG incurs various non-salary expenses on behalf of the CC. On a monthly basis, UNMMG provides the CC an electronic file with the detail and supporting invoices. The CC reviews and approves each expense before it is charged to the CC accounts. During FY13, UNMMG charged $6.3 Million to UNM CC for salary and other expenses.

CREDENTIALING AND SANCTIONS CHECK

The Office of Clinical Affairs serves as the credentialing and privileging hub for UNM HSC. They are responsible for credentialing and re-credentialing members of the Medical Staff and other health care professionals as outlined in the Medical Staff bylaws and related documents.

Various federal agencies have “exclusion lists” that contain individuals or businesses that are prohibited from doing business with the federal government. The persons and entities on each exclusion list are included on those lists because they broke the law due to healthcare fraud, certain drug offenses, or accusations of terrorism. Because UNM HSC receives money from the federal government, they are prohibited from hiring or contracting with excluded parties. For that reason, sanction checks are performed upon initial hire and on a continual basis.

During FY13 there were 72 billable providers at the CC.

MD Credentialing Process/Requirements

The Credentialing and Privileging Office is an office within the Office of Clinical Affairs and is a Centralized Verification Office. They are charged with credentialing for UNM HSC, UNMH, Sandoval Regional Medical Center (SRMC) and the UNMMG. The CC physicians are employees of the UNM HSC. Any physician that wants to practice at any of the areas goes through the Centralized Verification Office. The Credentialing and Privileging Office is responsible for the “onboarding process,” the process required to get physicians to the point where they can begin practicing at UNM facilities.

The following is an overview of the credentialing process in sequential order:

- Department Credentialing Coordinator works with the doctor to complete a Credentials Application Form
- Application submitted to the Department Chairman for review/approval
- Application forwarded to the Credentialing and Privileging Office for review process
    - Clinical Affairs completes a Primary Source Verification. The Primary Source Verification includes:
        - Current competency verification - by way of a form sent to the most recent employer for completion, basic attestation to the competency of the doctor.
        - License review/verification.
        - Various website checks: National Practitioner Data Bank, New Mexico Medical Board website.
- Credentials Committee review/approval.
- Medical Executive Committee review/approval.
- Performance Oversight Committee (designated committee by the HSC Board of Trustees) review/approval.

The Credentials Committee is made up of twelve physicians. If the Credentials Committee review is favorable, the summary of recommendation and file is passed forward to the Medical Executive Committee, made up of twenty five voting members. Once cleared by the Medical Executive Committee, the summarized application with a vote of confidence is forwarded to the Performance Oversight Committee (POC). The POC is comprised of five medical staff members and a community member. Once approved by the POC, physicians can begin practicing. The final review by the HSC Board of Trustees has been delegated to the POC by way of the medical staff bylaws.

There is a continual review process. Every eight months there is a documented Ongoing Professional Practice evaluation that is to be completed by the physician's home department. The department is charged with performing a chart review and an interpersonal evaluation. The report is kept at the department to be reviewed during the "re-appointment" review performed by the Credentialing and Privileging Office every two years. The National Practitioner Data Bank is checked again and all licenses are checked for expiration.

The credentialing process takes into account compliance with the following accreditation standards:

- Joint Commission Standards – Accredits the UNM Hospital
- National Committee on Quality Assessment Standards
- Center for Medical Services Standards
- Del Norte Vista Standards (for the Sandoval Medical Regional Center physicians)
- American Ambulatory Accreditation of Health Care (for the Medical Group staff)

- New Mexico Department of Insurance

Internal Audit judgmentally selected six active providers from the CC provider list and reviewed the credentialing files for completeness with regard to required documentation and appropriate approval levels. There were no exceptions noted. Each credential file reviewed contained all required documents and evidence of appropriate committee review and approvals.

Initial and On-going Sanctions Check

Sanctions checklists are performed when a provider is initially hired, and the checklists kept in their credentialing file. Sanctions tests are performed on an on-going monthly basis; the task is performed by two offices. The Office of Clinical Affairs performs ongoing sanction checklists on UNMH active providers. HSC Compliance Office performs ongoing sanction checklists on UNMMG active providers. All records and files are kept in their respective offices.

Both offices employ various methods to perform sanctions checks, including: CornerStone Health Care Services (a contracted vendor), the Office of Inspector General (OIG) website, and the System Award Management website. The OIG website performs an exclusion search. The System Award Management website is used to check whether or not an individual has been excluded from a federally-funded health care program. Any potential matches are researched further and results are kept on file. To date, there have been no confirmed matches by any of the source databases.

Internal Audit judgmentally selected six doctors from the CC's FY13 provider list and verified that initial and most recent ongoing sanctions checks had been performed. There were no exceptions noted. Each credential file reviewed contained documentation of the initial sanctions check. Review of the ongoing sanctions check revealed that the doctors selected were included on the list of providers verified against sanctions lists, and no matches were documented.

MEMORANDUMS OF AGREEMENT

Internal Audit had obtained a listing of UNM Cancer Center MOAs from CC Management. Internal Audit selected one out of the list of twenty one MOA's, the UNM Hospitals – Rapid Response Team MOA, for review and verification of compliance with the terms of the MOA.

The Rapid Response Team MOA pertains to an agreement between the CC and UNMH. The UNM Cancer Center requested the utilization of UNMH's Rapid Response Team for medical patient emergencies. The Team is responsible for calls on patient's physical condition and transportation. The MOA has reimbursement guidelines that included:

- Cancer Center will reimburse UNM Hospital salaries, wages, and 30.33% benefits for 0.5 FTE of the Rapid Response Team;
- Salaries and wages are to be reimbursed for twelve months ended June 30, 2012 and June 30, 2013;

- Total reimbursement amount will be $35,878.29 with salaries of $27,528.80 and benefits of $8,349.49;
- Invoices will be created by UNM Hospital to be sent to UNM Cancer Center on a monthly basis;
- Payment will be made to UNM Hospital within forty five (45) days of receipt.

Cancer Center Management and UNM Hospital Finance Department were contacted to obtain the Rapid Response Team MOA invoices and supporting documentation for calendar year 2013. The UNMH Finance Director indicated that the Rapid Response Team MOA was never billed by UNM Hospital for fiscal years 2012 and 2013. The omission of billing for the MOA was discussed with CC Management.

In order to preclude a similar situation from occurring in the future, the CC has assigned an accountant to perform an inventory of all current and in-progress MOAs for the CC. Once all MOAs have been reviewed and determined as active MOAs for the CC, they will be scanned and entered into a centralized database for MOA record keeping. The MOA centralized database will require a few months to complete.

Internal Audit and CC Management agreed that Internal Audit will review the MOA centralized database when it is completed. A consensus of a six month timeframe for the MOA centralized database to be ready was agreed upon by Internal Audit and CC Management.

DRUG INVENTORY AND RECONCILIATION

Prior to August 2009, the CC operated two infusion clinics, one was located at UNM Hospitals and the other was located at Lovelace Medical Center. In August 2009, the CC moved from UNMH to its current location at Camino de Salud. As a mutual decision between the CC and UNMH, the Adult Infusion Suite operates as a hospital based clinic. As a result, certain operating and financial responsibilities are designated to UNMH employees. One of the responsibilities delegated to UNMH employees is the inventory reconciliation process for high dollar drugs and the reconciliation from dispensed drugs to billed charges for those high dollar drugs.

The drug reconciliation process is a unique process throughout the UNM Health System. This process, led by the UNM CC Chief Medical Officer, has been a collaborative effort between the CC pharmacy, UNMH revenue initiatives department, and CC billing department. It is the only location that currently uses this process and has evolved over the past three years.

At its inception, the process was done manually on a month end basis. To increase accuracy and timeliness, the process was converted to weekly reconciliations beginning March 2011. It is a robust process. Although efficiencies have been gained through the use of technology and increased automation through Excel spreadsheets, it continues to be a very manual process that requires a significant amount of time.

The Medication Oncology Sub-committee approves a list of drugs that will be reconciled to determine completeness and accuracy of inventory and billing. The decisions for adding and/or removing drugs to the reconciliation process are based on Cardinal purchase history – total expense/individual cost.

There are two tiers in the reconciliation process:

- Inventory to Dispensed
- Dispensed to Billed

On a daily basis, the pharmacy prepares a report that lists the drugs based on inventory tracking system (Pyxis), Mosaiq Patient Schedule Report, and DoseEdge reports and drug wastage. When single dose vials are used, drug waste is recorded in a pharmacy waste note in the patient record and waste is coded according to the waste note.

On a weekly basis, UNMH revenue initiatives staff reconciles the inventory based on the beginning count of weekly inventory, purchases and dispenses. The billing data for that same service week is compared to the inventory reconciliation reports to identify billing variances. This process identifies any instances where the units billed do not match the drug dispensed. Variances are reviewed against the patient medical record and the coding summary to verify that the units billed are supported in the patient's medical record. If the billed units do not correlate to the medical record the billing is corrected.

Our audit included review of three monthly reconciliations to:

- Determine if the list of drugs identified by the Medication Oncology Sub-Committee is reconciled.
- Ensure the daily list that pharmacy prepares showing drugs administered and the drug wastage report are updated daily and include the drugs that are required to be reconciled.
- Test the inventory roll-forward to ensure that the calculated drugs dispensed equal the actual drugs dispensed per inventory tracking system (Pyxis) and if any variances exist they are reviewed, investigated and inventory is adjusted, as necessary.
- Review the dispensed to billing report to ensure that: 1. The drugs approved by the Medication Oncology Sub-Committee are included on the report; 2. The dispensed inventory matches the amounts on the inventory report; 3. The drugs identified by Pharmacy as administered to the patient are included in the dispensed drug list; and 4. If a variance exists between the dispensed report and the billing report it is reviewed, investigated, and appropriate adjustments are made to the patient billing record.

Policies and Procedures

It was noted that the committee has not established written criteria on the drugs that will be reconciled or the frequency to update the reconciliation list. The original plan was to include any medication that met one of two criteria. Either the cost of the medication was in the top 90% of the total drug spend as per the Cardinal 80/20 report, or the acquisition cost of the medication was greater than $100 per unit. It was noted that the drugs that are reconciled represent greater than 90% of the drugs purchased; however, they may not be in the top 90% of the purchase. Additionally, we noted that not all drugs greater than $100 per unit are reconciled.

Written policies and procedures provide the basic framework needed for establishing accountability. Without adequate written policies and procedures, management cannot ensure that controls are operating effectively.

Recommendation 2

The Director of Pharmacy and the Oncology Finance Director should establish written policies and procedures regarding the specifics of the drug reconciliation process, to include what drugs will be reconciled and how often the top drug list will be reviewed.

Response from the Director of Pharmacy and the Oncology Finance Director

Action Items: *Management recognizes that a formal policy was not properly documented for this reconciliation process. Please note that the reconciliation list has always been reviewed with and approved by the UNM Cancer Center Chief Medical Officer (CMO). With the guidance of the CMO, the Oncology Medication Sub-committee was established in the spring of 2011 to evaluate medications relevant to the practice of oncology for appropriate formulary designation which includes an evaluation of both safety and efficacy. The multidisciplinary venue afforded by the Oncology Medication Sub-committee also became a forum for discussions related to the inventory reconciliation process including the reconciliation list. In October of 2013, the schedule was changed to bimonthly which is the current schedule.*

Furthermore, it was determined that the top drug list for drug reconciliation will be reviewed and approved on a bi-annual basis by the Oncology Medication Sub-committee; this change will align the review process with key events such as the organization's biannual inventory, while also allowing for consideration of quarterly updates from Medicare, such as changes in the billing units of a medication or the assigned billing code. This review process will incorporate data from the 80/20 purchase reports from both Cardinal Specialty and regular Cardinal purchases for the previous six months. The top 90% of all Cardinal purchases and all drugs greater than $100 per unit will be presented to the sub-committee. The sub-committee will review and any exceptions will be noted and included in the minutes. The approved list will be effective in the drug reconciliation process in the month following approval and available for

future reference as part of the Oncology Medication Sub-committee minutes. This sample population criteria represents the highest volume and highest dollar drugs and sufficiently addresses overall materiality.
Targeted Completion Date: *2/13/14*
Assigned to: *Director of Pharmacy and the Oncology Finance Director*
Corrective Action Planned: *UNM Cancer Center has developed a formal policy surrounding the timing and the criteria of the drug reconciliation list. The Drug Reconciliation Process was revised to include the following elements:* • *This review process will incorporate data from the 80/20 purchase reports from both Cardinal Specialty and regular Cardinal purchases for the previous six months.* • *The top 90% of all Cardinal purchases and all drugs greater than $100 per unit will be presented to the sub-committee. The sub-committee will review the list and any exceptions will be noted and included in the minutes.* • *The approved list will be effective in the drug reconciliation process in the month following approval and available for future reference as part of the Oncology Medication Sub-committee minutes.* *Attached is the approved policy and procedure for the drug reconciliation process, revised on 2/6/14 and was formally approved by the Oncology Medication Sub-committee on 2/13/14.*

Reconciliation of Drugs Administered to Billed

There are three primary reports that are used to reconcile the drugs that were dispensed and billed. It was noted for all three months tested that the pharmacy report was not reconciled to the inventory report or the usage to billing report.

As a result, the pharmacy may be generating data that may pose a risk to dispensed inventory as it may not be reconciled to patient billing. We did not identify any drugs administered or dispensed that were not billed, however, there should be a reconciliation process between the drugs that the pharmacy identifies as being administered to the inventory roll-forward and to the billing report. This is will ensure that drugs identified as being administered are billed.

Recommendation 3

The Director of Pharmacy and the Oncology Finance Director should ensure that the reconciliation process includes reconciling the list that the pharmacy generates for drugs administered to the inventory listing and billing report.

Response from the Director of Pharmacy and the Oncology Finance Director

Action Items: *Management agrees with the recommendation and has already implemented the corrective action plan.*
Targeted Completion Date: *Implemented in January 2014 for the reconciliation week of December 9, 2013*
Assigned to: *Director of Pharmacy and the Oncology Finance Director*
Corrective Action Planned: *The drug reconciliation is designed to ensure that all drugs identified as administered are billed. The three reports that are used in the reconciliation process are the "pharmacy inventory report", the "inventory roll-forward report" and the "usage to billing report." For clarity, this is a multi-tiered reconciliation process. The data passes multiple levels of reconciliation by Pharmacy and Revenue Initiatives before the final billing report is generated. During this process usage and inventory anomalies were identified and removed from the billing report to prevent duplicate work at the next level. It is important to note that all potential billing variances are researched. In response to your recommendation, the reconciliation process now maintains a complete report of all variances and anomalies and provides a status comment as to the outcomes. This will ensure completeness of our process.*

CLINICAL TRIALS

Clinical trials are studies that evaluate the effectiveness of new drugs or treatment strategies. The development of more effective cancer treatments requires that new and innovative therapies be evaluated with cancer patients. Each clinical trial is designed to find new or better ways to treat cancer patients. In oncology, clinical trials are especially important because, in the absence of high cure rates, nearly all therapeutic approaches are developmental in nature.

Currently, there are hundreds of ongoing clinical trials in the United States. Although clinical trials are an important component of cancer care and are crucial for improving cancer treatment, fewer than 5% of cancer patients currently participate in clinical trials, because: they are uninterested or unaware that they exist; they have difficulty finding an appropriate clinical trial that may be of benefit to them; or they are ineligible to participate in a clinical trial because of prior treatment interventions.

At the CC there are three different categories for UNM clinical trials:

- Government Funded trials – National Cancer Institute (NCI)
- Industry Sponsored trials – biotech/pharmaceuticals
- Investigation Initiated trials

There are three stages of a clinical trial: identify and obtain approval for clinical trial, open the trial, and close the trial.

Identify and Obtain Approval for Clinical Trial

- A lead researcher/investigator or sponsor initiates a clinical working group for a specific trial. This may include research presentations, interviewing members from the community for eligibility in trial, explaining what the trial will accomplish and how it will be conducted, and specific training;
- Protocol and Monitoring Committee will review every clinical working group, including members from the community;
- An Institutional Review Board (IRB) will provide a neutral review and approve/disapprove trial. An IRB is responsible for overseeing any clinical trial that is performed in a specific healthcare institution where the clinical trial is conducted.

Open Clinical Trial Study

When the money is received, the lead investigator will enroll patients and begin the clinical trial work. The lead investigator will create a working manual to train staff and patients for the clinical trial. The research staff will screen patients and record all pertinent study information. If a study does not close in year, its status will remain open.

Each year an annual review of all studies is performed by the NCI. The UNM Cancer Center has an Internal Quality Assurance Committee that specifically reviews all clinical trials for compliance, amendments, and key performance indicators as specified by the NCI. The NCI comes on site to the CC every three years to conduct an audit of facilities and eligible patients. There are two employees at the CC that re-perform the NCI audit process and review all the clinical trials that are open and ongoing on an annual basis. Their audit includes reviewing actual studies and their measurement progress, compliance with NCI trial guidelines, and if the lead investigator is billing correctly. If an issue should arise, the lead investigator will correct the issue immediately.

Close Clinical Trial Study

A clinical trial may not close until all patients being monitored for a specific trial have been completed. It is typical for a trial to complete field work and remain open due to ongoing tests for patients. For example, a breast cancer patient may need to routinely come in for check-ups and the clinical trial will continue to monitor the patient, however the clinical trial will not perform any new trials on other breast cancer patients.

The NCI will use part of the grant funding to keep the study open for follow ups on patients. All information regarding the ongoing patients is recorded in a case report forms database and will be updated. All clinical trials are required to submit all pertinent clinical trial information on a monthly summary. The consequences for not adhering to NCI guidelines is closing the trial.

UNM Cancer Center is responsible for closing Government Funded trials and Investigation Initiated trials when all patients and on-going patients are completed with trials. The Cancer Center Alliance, not the CC, is responsible for closing all Industry Sponsored trials.

Clinical Trial Payments

NCI will provide grant funding for government funded clinical trials. The CC's Industry Sponsored clinical trials are paid through the New Mexico Cancer Care Alliance. The Cancer Care Alliance will pay 25% of CC salaries and benefits for the individuals working on the Industry Sponsored clinical trials. The CC and New Mexico Cancer Care Alliance have an agreement for this payment, which is updated on annual basis, as needed.

Clinical Billings

The New Mexico Cancer Care Alliance provides access to clinical trials in New Mexico. The New Mexico Cancer Care Alliance is comprised of physicians from both private practice and the following major healthcare systems: Christus St. Vincent Regional Medical Center, Lovelace Health Systems, Memorial Medical Center, New Mexico Veterans Affairs Medical Center, Presbyterian Healthcare Services, Southwest Gynecologic Oncology Associates, and the UNM CC. New Mexico does not have enough volunteer people for clinical trials and the New Mexico Cancer Care Alliance is able to use patients from each New Mexico county as part of clinical trials. There are agreements between the CC and the Cancer Care Alliance that allow the Cancer Care Alliance to interact with pharmaceutical companies, and the CC gives the Cancer Care Alliance the power to sign on its behalf for research services with pharmaceuticals. The Cancer Care Alliance bills the pharmaceutical companies or invoice company sponsors, and the money that Cancer Care Alliance receives goes to the CC.

Specific indexes are designed for all submissions to pre-award for clinical trials. The CC Program Manager assigns the fund according to index and budgeted amounts. The VELOS system, a clinical trials management software system, is utilized to assign a guarantor number and index assignment for each clinical trial. In the VELOS system, when additional funds are received from the Cancer Care Alliance, the CC Program Manager can assign it based on the guarantor number and index, since each is unique for every clinical trial.

The Cancer Center Alliance has several consultants that review each billing sent to the pharmaceutical companies or company sponsors. The consultants will review for any charges that could be collected from Medicare, what can be billed in the clinical trial, or patient only billing.

The CC completes a weekly review of all charges to the guarantor number and patients on study. In addition, a monthly reconciliation of the amount billed by the Cancer Center Alliance to the amount received is completed. The Cancer Care Alliance uses the VELOS system to bill pharmaceutical companies or company sponsors. The Cancer Care Alliance must pay the money it receives for clinical trials to the UNM Cancer Center within 45 days of receiving the funds.

Internal Audit selected two CC clinical trials, INST 1211 and E2496 for testing. The INST 1211 clinical trial is a non-treatment study that is focusing on questionnaires submitted by clinical patients for a new trial study regarding high cholesterol and specific types of cancer. The clinical patients will either take a placebo or prescription drug approved for this study and the patients will document their experiences based on a survey questionnaire. The trial has seventeen patients that are being monitored and results are being kept for each patient.

E2496 is a treatment study with Hodgkin's Disease patients for various effects of different types of chemotherapy and radiotherapy. The trial is closed to accrual study as of July 31, 2012. This means that the study has closed to accepting new patients and will remain open only to monitor the two clinical patients until they withdraw from the clinical trial or pass away. The trial still receives funding for salaries and incidental expenses to monitor the two clinical patients.

Internal Audit obtained the clinical trial protocol/agreement and reviewed it for notice of award/approval to begin clinical trial, necessary reporting requirements, money draw downs, clinical trial closing objectives, and IRB review guidelines. It appears INST 1211 and E2496 are in compliance with clinical protocols, notice of awards to open clinical trial, all IRB reviews, reporting requirements, financial draw downs, and notification of closures or extension of a clinical trial.

BIO-HAZARDOUS MATERIAL SAFETY

The Safety and Risk Services Department (SRS) is charged with oversight of tracking and disposal of chemicals. Until November 2013, SRS was also responsible for bio hazardous materials. Bio hazardous material waste management was transferred to the HSC Radiation Safety task force on November 1, 2013.

The current process is that each chemical should have a Medical Data Sheet containing specific critical information about each chemical, and each chemical should be properly labeled. SRS has a schedule for pickup of chemicals at various University locations. The CC is on a weekly schedule, unless SRS is called out prior to the next scheduled weekly pick up. SRS has a specific van to commute chemical waste. Chemical waste is picked up from the location, signed for, and housed/stored at SRS in locked storage at proper temperatures until it is transferred to one of the two contractors for disposal. PSC and Clean Harbors are the two vendors used for chemical disposal. Vendors pick up the chemical waste from SRS every 90 days. At the time of transfer from SRS to the vendor, a manifest is created, an SRS employee is present during the pick-up, and the employee signs off on the manifest to ensure accountability of all chemical waste transferred over to the vendor for disposal. Later, when the vendor invoices SRS, the invoice is reconciled to the manifest to ensure proper billing. SRS pays the vendor and then bills each department according to the waste they had removed.

Internal Audit reviewed a month of the SRS pick up schedule and verified vendor invoice support for the total amount charged to the CC. No exceptions were noted. The CC was not billed for any bio hazardous waste removal for FY13. They were billed $61,181 for Chemical/Infectious waste removal; that amount represented 6.7% of the total cost of Chemical/Infectious waste removal University wide.

APPROVALS

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Approved for Publication

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