October 2, 2015

LORI DONALDSON Chief Finance Officer UC San Diego Health System 8987

Subject: Charge Description Master Research Rate Review

Audit & Management Advisory Services Project 2015-18

The final audit report for Charge Description Master Research Rate Review, Audit Report 2015-18, is attached. We would like to thank all members of the department for their cooperation and assistance during the audit.

The findings included in this report will be added to our follow-up system. We will contact your staff 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 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. We also request that draft reports not be photocopied or otherwise redistributed.

David Meier Director Audit & Management Advisory Services

#### Attachment

cc: John Bainbridge

Margarita Baggett Cassi Birnbaum David Brenner Judy Bruner Kim Gillespie Laura Handy-Oldham

Andrea Kellogg
Patty Maysent
Sheryl Vacca



# **AUDIT & MANAGEMENT ADVISORY SERVICES**

# Charge Description Master Research Rate Review October 2015

## **Performed By:**

Nai Hwang, Auditor Christa Perkins, Manager

#### **Approved By:**

David Meier, Director

Project Number: 2015-18

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## I. Background

Audit & Management Advisory Services (AMAS) has completed a review of the Charge Description Master (CDM) Research Rates as part of the approved audit plan for Fiscal Year 2014-15. This report summarizes the results of our review.

The CDM is a master file that contains a combination of internally defined and industry standard data elements necessary to translate clinical services provided to patients into charges for subsequent billing and reimbursement of these services. The CDM includes standard rates and research rates. UC San Diego Health System (UCSDHS) Medical Center Policy 723.1 *Charge Description Master Maintenance* states that departments/cost centers are responsible for reviewing and updating their CDM annually. The CDM Manager is available to assist with these reviews.

In the past, UCSDHS had an agreement with the Department of Health & Human Services (DHHS) for approved research rates for patient care services provided in the inpatient environment at the General Clinical Research Center (GCRC). These rates were also used for other federal agreements. The last DHSS agreement expired on June 30, 2010. That same year, the GCRC ceased operation and cancelled all hospital beds reserved for clinical study. UCSDHS administration subsequently confirmed with DHHS that based on this change, an agreement was no longer required.

National Institutes of Health (NIH) Grants Policy Statement, II. B. 19 *Research Patient Care Costs* states that "research patient care costs, whether expressed as a rate or an amount, shall be computed in an amount consistent with the principles and procedures used by the Medicare program for determining the portion of Medicare reimbursement based on reasonable costs."

UCSDHS' practice is to utilize Medicare rates as research rates rounded up to the nearest whole dollar, when Medicare rates are available. When not available, research case rates are typically calculated based on direct cost plus 20%. For professional fees, the UC San Diego Medical Group sets research rates at the Medicare rates for government research sponsors, and 120% of the Medicare rate for commercial sponsors.

As of March 2015, the CDM contained approximately 4,700 Current Procedural Terminology (CPT) codes. A review of research charges posted in calendar year 2014 indicated that research charges totaled \$839,420 among 422 CPT codes. Approximately 73% of the transactions were for laboratory services, and this represented 39% of the research charges during this period. A summary of the research charge activity is provided in the table below.

2014 Posted Research Charges	Number of CPT Codes	Transaction Count	Total Charges	Percent of CPT codes	Percent of Transaction Count	Percent of Total Charges
Lab <b>(1)</b>	204	33,703	\$328,847	48%	73%	39%
Non- Lab	218	12,488	\$510,573	52%	27%	61%
Total	422	46,191	\$839,420	100%	100%	100%

<sup>(1)</sup> Generally, Laboratory uses CPT codes in the 80000 series.

### II. Audit Objective, Scope, and Procedures

The objective of our review was to review Epic CDM research rates, compare selected CPT codes to the latest published research rate schedule for consistency, and evaluate the effectiveness of overall CDM management processes. The focus of this review was on hospital (technical) services, although information on processes for professional fee research rates was also considered.

In order to achieve our objectives we completed the following:

- Interviewed the CDM Manager to obtain information on CDM maintenance processes and management;
- Reviewed applicable federal requirements and University policies including, but not limited to:
  - Centers for Medicare & Medicaid Services Decision Memo for Clinical Trial Policy, July 2007;
  - ➤ National Institutes of Health Grants Policy Statement, II. B. 19 Research Patient Care Costs;
  - ➤ UCOP 95-05, Requirement for Administration of Agreements with Private Sponsors for Drug and Device Testing Using Human Subjects; and
  - ➤ UCSDHS MCP 723.1, Charge Description Master Maintenance, effective October 2011.
- Reviewed and discussed research rate practices and DHHS agreements with the Director of Reimbursement, the Director of Budget/Financial Forecasting, Interim Director for Revenue Cycle Administration and the CDM Manager;
- Conducted interviews with the Laboratory Compliance Manager to gain an understanding of laboratory research rate charges and price maintenance;
- Met with the Medical Group Billing Manager and staff regarding research billing for professional fees;
- Reviewed research rate charges posted in 2014 for credit charges, procedures, cost centers;
- Selected 24 CPT codes for technical services based on volume or total charge amount for detail testing;
- Compared selected procedural research rates with 2013 and 2014 Medicare rates;
- Analyzed research rates charges (*Attachments A and B*); and
- Contacted other UC campuses for information on their research rate policy and practices.

#### III. Conclusion

We concluded that CDM research rates were generally consistent with published Medicare rates, and therefore compliant with the NIH grants policy statement for federally funded research. However, due to implementation of the Epic financial application in 2013, the annual research rate update process was not conducted for Fiscal Years (FY) 2013/14 and 2014/15. The lack of timely updates increased the risk of noncompliance with applicable regulatory and policy requirements. Our selected sample review revealed that while there were some differences in research rates as compared to Medicare rates, the overall financial impact for these research charges posted in 2014 to federal awards did not appear to be materially significant. The CDM team completed updating research rates FY 2015/16 in July 2015. We noted in review of pricing structures from peer institutions, that some other institutions implemented a higher research rate for commercially sponsored research. Multiple tiers for research rate charges could assist in recovering actual cost of providing these services, in light of University policy requiring research from commercial sponsors to be fully funded.

We also concluded that the current MCP 723.1 Charge Description Master Maintenance did not reflect the current applications and procedures for CDM maintenance. Also, an analytical tool that had been used prior to Epic implementation was not functioning effectively to assist in Medicare rate review in the new environment.

### IV. Observations and Management Corrective Actions

#### A. Research Rate Update

Research rates were not updated for two fiscal years. This was not compliant with policy, and increased both regulatory and financial risk.

Policy (MCP 723.1) requires annual review of CDM rates to ensure accurate and up-to-date pricing for standard and research charges. Due to the Epic system implementation in October 2013, research rates were not updated for FYs 2013/2014 and 2014/2015.

Our review of research charges for 24 selected CPT codes indicated that research rates for 13 CPT codes were charged more than Medicare rates. In most cases, the differences were not material, and related to small-dollar laboratory charges. However, we noted one instance where the difference was over \$150, and two instances where the difference was over \$40. In addition, research rates for four CPT codes were lower than Medicare rates. A detailed listing of CPT codes reviewed and associated prices is provided in *Attachment A*.

We analyzed this population further to review research charges from these CPT codes to federally-funded research<sup>1</sup>, to evaluate compliance with the NIH grants policy statement. This analysis indicated that the majority of the charge variance was attributed to one CPT code for one study. A detailed summary by study and CPT code is provided in *Attachment B*. Additional review of the research agreements and multiple funding sources for this study will be needed to evaluate whether the rates charged were non-compliant with NIH guidelines.

Even though the financial impact may not be significant, the lack of timely research rate updates increased the financial risk that costs were not fully recovered, and risk of non-compliance with applicable policy and regulatory requirements.

#### **Management Corrective Actions:**

The CDM team completed updating research rates for Fiscal Year 2015/16 in July 2015.

The Research Compliance Program will evaluate the one study with a significant variance in research charges to determine whether corrective action is needed.

#### B. Research Rate Oversight

The current policy on Charge Description Master maintenance did not reflect the current applications and procedures. An analytical tool was not functioning effectively to assist in Medicare rate review.

#### Research Rate Policy & Pricing Methodology

Policy (MCP 723.1) states that each department is responsible for reviewing and ensuring that their CDM items are current and accurate. The CDM Manager is responsible for coordinating and assisting departments and cost centers to ensure compliance with federal, state and third-party regulations and requirements. We noted that this MCP was last updated in October 2011, and the policy did not reflect current applications and work processes which have since changed. We also noted that the University's approach for pricing research rates had not been formalized. A draft Technical Research Rate Development Guideline was developed in 2013, which outlined data elements, data sources, and research pricing procedures based on Medicare reasonable cost principles or direct cost plus 20%. The CDM Manager generally followed these principles for consistent pricing, however, this draft procedure was not formalized and shared with departments for implementation. A transparent research pricing procedure that

<sup>&</sup>lt;sup>1</sup> Data was evaluated for studies indicated in the Velos Clinical Trial Management System as "Federal (NIH,NCI, HHS, DoD, NSF)". This may indicate that research is funded in whole or part from federal sources, either as a direct award recipient or subcontractor.

allows for consistency and appropriate budgeting and contracting is essential to remain competitive in performing innovative clinical research and maintaining compliance with applicable laws and University policies.

In addition to ensuring compliance with regulations for appropriate costing of federally-sponsored research, the University is also required to ensure that commercially sponsored research is fully funded. For industry initiated agreements, UC Operating Memo 95-05 states that "the cost of clinical trials of drugs or devices conducted according to the sponsor's protocols should always be fully funded by the sponsor and may not be supported in whole or in part with other funds." Medicare rates are widely used as a research price base, however Medicare rate may not cover actual costs.

Our research noted that some other institutions either implemented or considered multiple tiers of research rates based on the sponsorship. For example, one comparable institution defined research rate pricing that was determined by the source of clinical study funding and support. For a non-profit clinical study, research pricing was based on the DHSS rate agreement. For a for-profit clinical study, the research rate was set on 150% of applicable Medicare reimbursement. This pricing structure was implemented in order to minimize institutional risk of charging for-profit entities less than government sponsors, and minimize risk of deficits caused by not recovering full costs of research procedures.

In addition, we noted that current practice is to update the CDM as of July 1, to coincide with the new fiscal year. However, Medicare rates are issued on a calendar year basis, effective January 1 of each year. As a result, there is a 6-month window when these rates differ. Modifying CDM research rate update processes to a calendar year basis would eliminate these variations.

#### **Management Corrective Actions:**

The CDM team will

- 1. Update policy (MCP 723.1) for current applications and processes.
- 2. Finalize the Technical Research Rate Development Guideline and provide to the departments and cost centers when developing research rates.

As part of the review of the above, consideration will be given to changing the timing of CDM rate updates to a calendar year basis, and evaluating whether multiple tiers for technical research rates based on sponsor type would be appropriate.

### **MedAssets Application**

Medicare rates are formulated based on a common rate plus other factors, such as area wage adjustments. In order to obtain and confirm Medicare rates, an analytical application (MedAssets) was used prior to Epic implementation to corroborate Medicare rates and review invalid CPT codes on a routine basis. However, the CDM file format from Epic was not provided in a format compatible with MedAssets. Therefore this tool has not been utilized since the Epic implementation, although the University continues to pay for the application. Without a working analytical tool, evaluation of research rates for consistency with Medicare rates was hindered. This tool would also greatly assist in the annual update of clinical (non-research) rates, by improving efficiency and reducing the otherwise manual comparison of rates.

#### **Management Corrective Action:**

The Department will configure the CDM price file format to be compatible with use of the MedAssets application, to allow for the additional analysis and verification of clinical and research rates to Medicare rates.

Attachment A - 2014 Research Rate Charges Review Summary

Procedure Code	CPT Code (1)	Total Volume	Total Amount	R	2014 CDM Medicare Rate Research Rate (July 2014) (2)		Round up Medicare Rate (July 2014) (3)		Variances	
2694	93306	113	\$34,970	\$	658	\$	501.15	\$ 502	\$	156
1419	70491	47	\$12,448	\$	336	\$	292.06	\$ 293	\$	43
1452	71260	128	\$38,152	\$	336	\$	292.06	\$ 293	\$	43
3207	C8908	37	\$33,622	\$	598	\$	578.16	\$ 579	\$	19
1596	74177	115	\$51,050	\$	650	\$	643.09	\$ 644	\$	6
2721	93460	5	\$15,200	\$	3,040	\$	3,034.32	\$ 3,035	\$	5
2384	87536	222	\$19,844	\$	121	\$	116.09	\$ 117	\$	4
2368	87340	864	\$5,704	\$	17	\$	14.10	\$ 15	\$	2
2055	81001	925	\$6,442	\$	7	\$	4.32	\$ 5	\$	2
4574	86780	1,546	\$6,724	\$	20	\$	18.06	\$ 19	\$	1
2191	85025	4,648	\$23,741	\$	12	\$	10.61	\$ 11	\$	1
2133	82977	823	\$7,490	\$	11	\$	9.82	\$ 10	\$	1
2091	82248	936	\$6,288	\$	8	\$	6.84	\$ 7	\$	1
2148	83735	1,033	\$9,080	\$	10	\$	9.14	\$ 10	\$	-
2185	84550	1,024	\$6,256	\$	7	\$	6.16	\$ 7	\$	-
2144	83615	1,043	\$7,974	\$	9	\$	8.23	\$ 9	\$	-
2139	83036	842	\$10,047	\$	14	\$	13.24	\$ 14	\$	-
2033	80061	929	\$12,711	\$	19	\$	18.27	\$ 19	\$	-
2226	85610	1,077	\$5,132	\$	6	\$	5.37	\$ 6	\$	-
2032	80053	4,006	\$29,109	\$	15	\$	14.41	\$ 15	\$	-
2959	99214	302	\$18,717	\$	107	\$	108.53	\$ 109	\$	(2)
2669	93005	374	\$13,507	\$	30	\$	31.81	\$ 32	\$	(2)
2925	96413	179	\$38,236	\$	233	\$	351.32	\$ 352	\$	(119)
977	47000	31	\$21,953	\$	757	\$	888.79	\$ 889	\$	(132)
	Total	21,249	\$434,397							

<sup>(1)</sup> Samples were selected based on high Total Volume and/or high Total Amount.

<sup>(2)</sup> Medicare Rate (July 2014) was obtained through MedAssets.

<sup>(3)</sup> Generally, a round-up Medicare rate was set as research rate.

#### Attachment B - 2014 Research Rate Charges Financial Impact Summary

Table 1 - Summary of Variances Between Research Charges and Medicare Rates For Federally Funded Studies for Selected CPT Codes, by Study and CPT Code

CPT Code =>	81001	82248	82977	85025	87340	87536	93306	93460	C8908	<b>Grand Total</b>
Study Number										
100222	\$389			\$67			\$156		\$16,831	\$17,443
91571		\$100	\$102	\$229						\$431
110960	\$30	\$88	\$90	\$11	\$54					\$273
130198		\$85	\$85	\$86						\$256
120586		\$32	\$54	\$51						\$137
61366				\$19		\$68				\$87
111282	\$22		\$13	\$12	\$30					\$77
71351	\$30	\$3		\$7				\$25		\$65
91797				\$11		\$52				\$63
110792	\$6			\$6		\$48				\$60
140084	\$12	\$6		\$7	\$30					\$55
140070				\$24						\$24
120576	\$6			\$7		\$8				\$21
110081		\$1	\$18							\$19
101152						\$8				\$8
120244				\$8						\$8
110263	\$2			\$5						\$7
101249				\$6						\$6
100116			\$3	\$2						\$5
101286				\$3						\$3
71164				\$2						\$2
80660				\$2						\$2
91037				\$2						\$2
81696				\$1						\$1
90979				\$1						\$1
140510				\$1						\$1
Total Variance	\$497	\$315	\$365	\$570	\$114	\$184	\$156	\$25	\$16,831	\$19,057

#### Methodology:

- 1. Calendar year 2014 posted research rate charges;
- 2. Selected 24 CPT codes based on volume or total charge amount;
- 3. Identified 13 CPT codes with Research Rates that were higher than the 2014 Medicare Rate (Attachment A);
- 4. Analyzed research transactions with Federal research type in Velos (Guarantor Type = Research and Research Type = Federal (NIH, NCI, HHS, DoD, NSF) for the 13 CPT codes;
- 5. Classified transaction by research rate charged;
- 6. Calculated the amount charged above the Medicare rate (excluding research rate charge credits). In some cases, there were no differences for Federal research studies.

#### Attachment B - 2014 Research Rate Charges Financial Impact Summary

Table 2 - Detail of Variances for Federally-Funded Studies, by CPT Code and Study

	s. d. N. orbo	Research	Medicare	Variance Between Research Charge &	Number of	Calculated	Total Variance by
	Study Number	Charge \$598	<b>Rate</b> \$579	Medicare Rate	Transactions 25	Variance	СРТ
C8908 C8908	100222 100222	\$4,668	\$579	\$19 \$4,089	4	\$475 \$16,356	\$16,831
81001	71351	\$7	\$5	\$2	15	\$30	710,031
81001	100222	\$7	\$5	\$2	43	\$86	
81001	100222	\$106	\$5	\$101	3	\$303	
81001	110263	\$7	\$5	\$2	1	\$2	
81001	110792	\$7	\$5	\$2	3	\$6	
81001	110960	\$7	\$5	\$2	15	\$30	
81001	111282	\$7	\$5	\$2	11	\$22	
81001	120576	\$7	\$5	\$2	3	\$6	
81001	140084	\$7	\$5	\$2	6	\$12	\$497
82248	71351	\$8	\$7	\$1	3	\$3	
82248	91571	\$8	\$7	\$1	100	\$100	
82248	110081	\$8	\$7	\$1	1	\$1	
82248	110960	\$8	\$7	\$1	88	\$88	
82248	120586	\$8	\$7	\$1	32	\$32	
82248	130198	\$8	\$7	\$1	85	\$85	
82248	140084	\$8	\$7	\$1	6	\$6	\$315
82977	91571	\$11	\$10	\$1	102	\$102	
82977	100116	\$11	\$10	\$1	3	\$3	
82977	110081	\$11	\$10	\$1	18	\$18	
82977	110960	\$11	\$10	\$1	90	\$90	
82977	111282	\$11	\$10	\$1	13	\$13	
82977	120586	\$11 \$11	\$10	\$1 \$1	54 85	\$54	¢26F
82977	130198	•	\$10		19	\$85	\$365
85025 85025	61366 71164	\$12 \$12	\$11 \$11	\$1 \$1	2	\$19 \$2	
85025	71104	\$12	\$11	\$1	7	\$7	
85025	80660	\$12	\$11	\$1	2	\$2	
85025	81696	\$12	\$11	\$1	1	\$1	
85025	90979	\$12	\$11	\$1	1	\$1	
85025	91037	\$12	\$11	\$1	2	\$2	
85025	91571	\$12	\$11	\$1	99	\$99	
85025	91571	\$76	\$11	\$65	2	\$130	
85025	91797	\$12	\$11	\$1	11	\$11	
85025	100116	\$12	\$11	\$1	2	\$2	
85025	100222	\$12	\$11	\$1	2	\$2	
85025	100222	\$76	\$11	\$65	1	\$65	
85025	101249	\$12	\$11	\$1	6	\$6	
85025	101286	\$12	\$11	\$1	3	\$3	
85025	110263	\$12	\$11	\$1	5	\$5	
85025	110792	\$12	\$11	\$1	6	\$6	
85025	110960	\$12	\$11	\$1	11	\$11	1
85025	111282	\$12	\$11	\$1	12	\$12	
85025 85025	120244	\$12	\$11 \$11	\$1 ¢1	8	\$8 \$7	
85025 85025	120576 120586	\$12 \$12	\$11 \$11	\$1 \$1	7 51	\$7 \$51	
85025 85025	130198	\$12	\$11	\$1 \$1	86	\$86	1
85025	140070	\$12	\$11	\$1	24	\$24	
85025	140070	\$12	\$11	\$1	7	\$7	
85025	140510	\$12	\$11	\$1	1	\$1	\$570
87340	110960	\$21	\$15	\$6	9	\$54	+3.0
87340	111282	\$21	\$15	\$6	5	\$30	
87340	140084	\$21	\$15	\$6	5	\$30	\$114
87536	61366	\$121	\$117	\$4	17	\$68	
87536	91797	\$121	\$117	\$4	13	\$52	
87536	101152	\$121	\$117	\$4	2	\$8	1
87536	110792	\$121	\$117	\$4	12	\$48	1
87536	120576	\$121	\$117	\$4	2	\$8	\$184
93306	100222	\$658	\$502	\$156	1	\$156	\$156
93460	71351	\$3,040	\$3,035	\$5	5	\$25	\$25
					Total	\$19,057	\$19,057

<sup>1.</sup> In some cases, research charges were noted at a rate that differed from the CDM Research Rate. This could be attributed to special case rates or contract pricing.