ADEA AMERICAN DENTAL EDUCATION ASSOCIATION

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Health Care Reform: Action in the Senate

The Senate continues to seek compromises on a health care reform plan that can garner the 60 votes necessary to break a Republican-led filibuster. By working on weekends, Senate Democratic leaders hope to pass reform legislation by Christmas. Progress is slow and tenuous, but liberal and moderate Democrats hope to pass a bill that expands coverage, restrains health care spending, and reduces the national deficit.

Earlier in the session, reform bills were passed by two Senate committees of jurisdiction. *America's Healthy Future Act of 2009 (*S. 1796) was approved by the Senate Finance Committee, and *The Affordable Health Choices Act (*S. 1679) was passed by the Senate Health, Education, Labor and Pensions (HELP) Committee. Both passed on a strictly partisan basis, and both included provisions that are important to academic dental institutions and oral health. On November 18, Senate Majority Leader Harry Reid (D-NV) unveiled *The Patient Protection and Affordable Care Act* (S.3590), a bill that merges S. 1796 and S. 1679. Reid's bill includes the provisions related to academic dental institutions and oral health that were included in the two earlier Senate reform bills. Last month, the Senate voted on a procedural motion to begin debate on health care reform. The vote passed by a margin of 60 to 39, and the Senate has been debating amendments since they returned from Thanksgiving break.

DENTAL RELATED PROVISIONS IN THE SENATE HEALTH CARE REFORM BILL (S. 3590)

Title I: Sec. 1302: Essential Health Benefits Requirements

Synopsis: Lists the general categories that health plans must offer if they want to participate in the health benefits "Exchange." The plans must offer pediatric oral health care services.

Title I: Section 1311: Affordable Choices of Health Benefit Plans (d)(B)(ii)

Synopsis: Allows standalone dental plans to offer a plan through the Exchange (either separately or in conjunction with a qualified health plan).

Title IV: Sec. 4101: School-Based Health Centers

Synopsis: Defines school-based health clinics, sponsors, and requirements of services that must be offered. The Centers must offer comprehensive health assessments, diagnosis, and treatment of minor, acute, and chronic medical conditions, and referrals to, and follow-up for, specialty care and oral health services.

Title IV: Sec. 4102: Oral Healthcare Prevention Activities (Sec. 399LL and 399LL-1)

Synopsis: Requires the Centers for Disease Control and Prevention (CDC) to establish a five-year national public education campaign that focuses on oral health care prevention and education, including prevention of oral disease such as early childhood and other caries, periodontal disease, and oral cancer. The CDC will award demonstration project grants for research-based dental caries disease management.

Title IV: Sec. 4102: Oral Healthcare Prevention Activities (b)(c)(d)

Synopsis: Establishes a grant program for all states, territories, and Indian tribes for school-based sealant programs; aims to improve the oral health infrastructure by requiring the CDC to enter into cooperative agreements with all states, territories, and tribal units of government to establish oral health leadership and program guidance and implement or improve oral health data collection and interpretation; updates national oral health surveillance activities, specifically: the Pregnancy Risk Assessment Monitoring System (PRAMS) must be have updated on how it relates to oral health; the National Health and Nutrition Examination Survey must be updated to include tooth-level surveillance; the Medical Expenditures Panel Survey must be updated to include the verification of dental utilization, expenditure, and coverage findings through conduct of a look-back analysis; and the National Oral Health Surveillance System must include the measurement of early childhood carries.

Title IV: Sec. 4203: Establishment of Standards for Accessible Medical Diagnostic Equipment

Synopsis: Requires standards to be established so individuals with disabilities can have access to medical diagnostic equipment. Chairs for dental examinations or procedures are included in the list of equipment that must have standards for accessibility.

Title V: Sec. 5101: National Health Care Workforce Commission

Synopsis: Creates a National Health Care Workforce Commission that would serve as a resource to Congress, the President, states, and localities by disseminating information on current and projected health care workforce supply and demand, workforce education and training capacity, best practices in health care career pathways and education, and a fiscally sustainable integrated workforce that meets needs of patients and populations. The education and training capacity, projected demands, and integration with the health care delivery system of the oral health workforce capacity at all levels is included as a high priority area.

Title V: Sec. 5303: Training in General, Pediatric, and Public Health Dentistry

Synopsis: 1) Creates a separate section, distinct from medicine, for dental training programs under Title VII Health Professions Programs; 2) Adds public health dentistry and dental hygienists to the dental section; 3) Reauthorizes the Title VII program; and 4) Makes dental schools eligible for federal grants for programs for which currently only medical schools are eligible.

The funds will be used to:

- Plan, develop, and operate a professional training program in the field of general dentistry, pediatric dentistry, or public health dentistry for dental students, residents, practicing dentists, dental hygienists, and other primary care dental trainees that emphasizes training for general, pediatric, or public health dentistry;

- Provide financial assistance to needy dental students, residents, practicing dentists, and dental hygiene students who are participants in such programs and plan to work in the practice of general, pediatric, public health dentistry, or dental hygiene;

- Plan, develop, and operate a program for the training of oral health care providers who plan to teach in general, pediatric, public health dentistry, or dental hygiene;

- Provide financial assistance in the form of traineeships and fellowships for those who plan to teach or are teaching in general, pediatric, or public health dentistry;

- Provide funds for the costs to establish, maintain, or improve dental faculty development programs in primary care (which may be departments, divisions, or other units);

- Provide funds to establish, maintain, or improve predoctoral and postdoctoral training in primary care programs;

- Create a loan repayment program for faculty in dental programs; and

- Provide technical assistance to pediatric training programs in developing and implementing instruction regarding the oral health status, dental care needs, and risk-based clinical disease management of all pediatric populations, with an emphasis on underserved children.

The section also creates a second faculty loan repayment program under which a grant or contract would be awarded to a program of general, pediatric, or public health dentistry to plan, develop, or operate a loan repayment program in dental schools, dental hygiene schools, residency and advanced education programs. Program funds must be offered to full-time faculty members.

Title V: Sec. 5303: Alternative Dental Health Care Providers' Demonstration Projects

Synopsis: Provides funds for 15 demonstration projects for programs to train or employ alternative dental health care providers in order to increase access to dental health care services in rural and other underserved communities. Alternative dental health care providers include community dental health coordinators, advanced practice dental hygienists, independent dental hygienists, supervised dental hygienists, primary care physicians, and dental therapists.

Title V: Sec. 5315: United States Public Health Sciences Track

Synopsis: Establishes a United States Public Health Sciences Track at sites to be selected by the HHS Secretary, with authority to grant appropriate advanced degrees in a manner that uniquely emphasizes team-based service, public health, epidemiology, and emergency preparedness and response. It shall be organized to graduate not less than 100 dental students annually (among other health care providers). The locations will accredited and affiliated with health professions education training programs at academic health centers located in regions of the United States determined appropriate by the Surgeon General, in consultation with the National Health Care Workforce Commission.

Title V: Sec. 5505: Rules for Counting Resident Time for Didactic and Scholarly Activities and Other Activities

Synopsis: Clarifies that the time dental residents spend in patient-related care activities, such as educational conferences and seminars, can be counted for Graduate Medical Education (GME) funding.

Title V: Sec. 5508: Increasing Teaching Capacity

Synopsis: Establishes a grant program for teaching health centers for the purpose of establishing new accredited or expanded primary care residency programs**.** General and pediatric dental residency programs would be eligible for these grants.

Health Care Reform: Passage in the House

On November 7, the U.S. House of Representatives passed *The Affordable Health Care for America Act* (H.R. 3962) by a vote of 220-215. One Republican, **Anh "Joseph" Cao** (R-LA), voted in favor of the bill. Thirty-nine Democrats voted against the legislation. For an analysis of the House-passed bill, please see the Special Edition of the *Washington Update,* Volume 7, No. 7, November 6, 2009.

FY 2010 Appropriations

Taking a momentary break from the national health care reform debate, congressional appropriators returned their focus to the unfinished Fiscal Year 2010 appropriations by wrapping up six incomplete appropriations bills into a single omnibus bill. Included in that bill were the Labor, Health and Human Services and Education appropriations that contain funding for dental programs under the Health Resources and Services Administration (HRSA), the National Institutes of Health (NIH), and the Centers for Disease Control and Prevention (CDC). The Labor-HHS-Education appropriations bill includes a total of $163.6 billion, an $8.5 billion increase over Fiscal Year 2009. It is nearly a $3 billion increase over the President's FY 2010 request ($160.706 billion) and is slightly higher than both the House passed and Senate committee versions ($163.4 and $163.1 billion, respectively).

Dental training and research programs receive significant increases:

- $15 million for general dentistry and pediatric dentistry residency programs, with both programs receiving not less than $7.5 million.
- $17.5 million for state grants under the Dental Health Improvement Act.
- $31 billion for the National Institutes of Health, a $692 million increase over FY 2009.
- $413 million for the National Institute of Dental and Craniofacial Research (NIDCR), an $11 million increase over FY 2009.
- $16.5 million for the Ryan White Dental Reimbursement Program, a $3 million increase. The dental reimbursement program has been flat funded for the last few years.

We anticipate final passage of the bill prior to December 18, 2009.

HIPAA Breach Notification

To review the American Dental Education Association's comments on the Department of Health and Human Service's interim final rule on Breach Notification for Unsecured Protected Health Information, as published in the Federal Register on August 24, 2009, go to page 14 of this issue of the **Washington *Update.***

NIH Final Rule

The National Institutes of Health (NIH) has released the final rule on "Grants for Research Projects." Effective December 10, the rule amends the current regulations governing grants for research projects by revising the definition of Principal Investigator (PI) to permit more than one individual with appropriate levels of authority and responsibility to be listed in the grant application.

The final rule allows multiple individuals to share responsibilities for the scientific and technical direction of a project when that more accurately reflects the management needs of the research project. It also emphasizes that each Principal Investigator is responsible and accountable to the applicant organization or, as appropriate, to a collaborating organization for the proper conduct of the project or program, including the submission of all required reports.

The rule permits the Secretary of Health and Human Services (HHS) to evaluate, approve, and make more than one award pursuant to one or more applications and provides examples of situations when the disaggregation of a single application into multiple awards would improve scientific and administrative management. NIH believes that this change in regulations will foster interdisciplinary and collaborative research and will improve management flexibility, even when components of such programs are administered by different NIH awarding components.

A National Medical Education Trust Fund?

As part of its ongoing discussions on Medicare payment policies and graduate medical education (GME), the Medicare Payment Advisory Commission (MedPAC) at its November 5-6 meeting focused on funding sources for graduate medical education. While MedPAC is still in a "discussion" phase, the Commissioners anticipate ultimately making recommendations in the Commission's June 2010 report.

A staff presentation discussed the concept of a "national medical education trust fund." Possible rationales presented for such a fund included the fact that the original Medicare legislation ultimately envisioned the "community" undertaking the costs of medical education and that the Medicare program is going insolvent. As envisioned by the staff, the purpose of the trust fund would be to aggregate resources "into an entity that can assess U.S. needs and allocate funds accordingly." The funds would come from Medicare, Medicaid, and general revenues and could be distributed to a variety of entities, including providers and potentially to residency programs as well.

During the discussion period, there were comments as to whether the Commission should take on a topic as broad and complex as the trust fund, or if it would be better to focus more precisely on specific (albeit potentially incremental) changes to graduate medical education Medicare policies. One Commissioner noted that even incremental changes may cause disruption to medical education training; therefore, very careful consideration needs to take place when trying to change the funding mechanism for medical education.

While many Commissioners agreed that using other sources to supplement the funding of medical education is a good idea, many expressed concern that the use of general revenues could lead to instability in payments, due to the unpredictability of the appropriation process. Several Commissioners also expressed concern that getting other payers to contribute to medical education would be difficult, especially if the approach involves new taxes.

HHS Faculty Loan Repayment Awards

The Department of Health and Human Services (HHS) announced awards totaling nearly $1.2 million to help health professions faculty from disadvantaged backgrounds repay their student loans. The funds are part of

$500 million appropriated to HHS' Health Resources and Services Administration (HRSA) by the American Recovery and Reinvestment Act (Recovery Act) to address workforce shortages and encourage greater diversity in the health professions.

The awards are made through HRSA's Faculty Loan Repayment Program, a loan repayment program specifically for health professions graduates from disadvantaged backgrounds who agree to serve as faculty at an eligible health professions college or university for a minimum of two years. The program provides up to $40,000 and covers tax liability in return for a two-year service commitment. To participate in this program, faculty members must serve at an accredited health professions college or university and have a degree in one of the following health professions: allopathic or osteopathic medicine; dentistry; optometry; pharmacy; podiatric medicine; veterinary medicine; nursing (RN only); public health; certain allied health disciplines (dental hygiene, medical laboratory technology, occupational therapy, physical therapy, radiologic pathology, speech pathology, audiology, and registered dietitians); and certain graduate programs in the behavioral and mental health disciplines (clinical psychology, clinical social work, professional counseling, and marriage and family therapy).

Faculty Loan Repayment Program Awardees

School	City	State	Discipline	Amount
University of Central Arkansas	Conway	AR	Occupational Health	$29,389.48
Alliant International University	Fresno	CA	Psychologist	$59,853.40
California State University	Fullerton	CA	Nurse	$59,853.40
Howard University	Washington	DC	Nurse	$59,853.40
Morehouse School of Medicine	Atlanta	GA	Physician	$59,853.40
Spaulding University	Louisville	KY	Psychologist	$59,853.40
Xavier University of Louisiana	New Orleans	LA	Pharmacist	$59,853.40
Xavier University of Louisiana	New Orleans	LA	Pharmacist	$59,853.40
Louisiana State University	New Orleans	LA	Nurse	$18,539.95
Montana State University	Bozeman	MT	Nurse	$59,853.40
Eastwick College	Hackensack	NJ	Nurse	$59,853.40
University of North Carolina	Charlotte	NC	Public Health	$59,655.88
University of Central Oklahoma	Edmond	OK	Nurse	$59,853.40
University of Central Oklahoma	Edmond	OK	Nurse	$25,913.69
Temple University	Philadelphia	PA	Podiatrist	$59,853.40
East Tennessee State University	Johnson City	TN	Nurse	$59,853.40
Meharry Medical College	Nashville	TN	Physician	$59,853.40
Meharry Medical College	Nashville	TN	Dentist	$59,853.40
Texas Southern University	Houston	TX	Public Health	$59,853.40
University of Memphis	Memphis	TX	Psychologist	$25,892.31
Westminster College	Salt Lake City	UT	Nurse	$59,095.92
Casper College	Casper	WY	Nurse	$59,853.40
				*Total: $1,176,141.63

Ryan White CARE Act Reauthorized

President **Barack Obama** signed the Ryan White HIV/AIDS Treatment Extension Act of 2009 into law on October 30, 2009, following the unanimous passage of the bill in the Senate and a 408-9 vote in the House of Representatives. The law includes:

- Four-year reauthorization and the removal of the "sunset" clause.
- 5% increase for authorized appropriations for sections A thru F, Part F (includes dental).
- Hold harmless levels for Part A and B grantees set at 95% for FY2010, 100% for FY2011 and FY2012, and 92.5% for FY2013.
- State exemption period for names-based reporting extended for three years, at which point all state and jurisdiction formulas will be based on living HIV/AIDS case reports.

- Unobligated funding thresholds raised from 2% to 5% and, under certain circumstances, allows the Secretary of Health and Human Services to waive unobligated requirements for rebates received from pharmaceutical companies.
- An early identification and testing component added, requiring planning councils to create a strategy to identify people with HIV/AIDS who do not know their HIV status and link them to Part A health and support services.
- Identification and linkage to care rewards in Part A supplemental grants; requires Part B grantees to create a similar plan.
- A national goal of 5 million "federally supported" tests annually.
- Reinstates language removed by the 2006 Treatment Modernization act requiring notification of emergency service personnel of exposure to airborne infectious diseases under certain circumstances.
- Minority AIDS Initiative (MAI) grants changed from competitive grants to a formula based on "distribution of populations disproportionately affected by HIV/AIDS"; synchronizes release of MAI grant awards with the release of awards.

Additionally, the House released report language in conjunction with the bill seeking to increase flexibility in spending and accountability for support services (such as public transportation vouchers for travel for services), highlighting use of funding for co-infection with hepatitis B and C, and encouraging ongoing research of HIV/AIDS vaccines.

Authorization Amounts for the Ryan White Program
($ in millions)

Ryan White Program Parts	FY2010 Authorization	FY2011 Authorization	FY2012 Authorization	FY2013 Authorization
Part A	$682	$716	$751.9	$789.5
Part B	$1,349.5	$1,417	$1,487.8	$1,562.2
Part C	$246.9	$259.2	$272.2	$285.8
Part D	$75.4	$79.2	$83.1	$87.2
Part F: AECTs	$36.4	$38.3	$40.2	$42.2
Part F: Dental	$13.7	$14.3	$15	$15.8
Part F: MAI	$146.1	$153.4	$161	$169.1
Total	**$2,550**	**$2,677**	**$2,811**	**$2,952**

For more information, funding authorizations, and a section by section description of the bill, please see the document produced by the House Energy and Commerce Committee at http://energycommerce.house.gov/Press_111/20091013/Ryan_White_Section.pdf.

To view the final language in the bill, go to http://thomas.loc.gov/cgi-bin/query/C?c111:./temp/~c111nrvSCf. [BAD LINK] Report language can be found at http://thomas.loc.gov/cgi-bin/cpquery/T?&report=hr305&dbname=111&.

HRSA Grants for RCWA Dental Programs

The Health Services and Resources Administration (HRSA) has awarded FY 2009 grants for the Ryan White Dental Reimbursement Program (DRP) and the Community-Based Dental Partnership Program. Unreimbursed costs total $25,524,815 across all applications. The amount available for DRP in Fiscal Year 2009 has been estimated to be $9,038,351. Awards were calculated by dividing the unreimbursed costs for each applicant by the total unreimbursed cost across all applications, then multiplying by the amount available for DRP. Applicants received 35.41% of the reported unreimbursed costs incurred while providing oral health care during the period July 1, 2007, through June 30, 2008.

FY 2009 Dental Reimbursement Program Awards					
Name	Organization	City/State	Type	Cost	Award Amount
University of Southern California	University of Southern California School of Dentistry	Los Angeles, CA	PreDoc	$1,441,755	$510,526.24
Regents of the University of California	University of California, Los Angeles School of Dentistry	Los Angeles, CA	PreDoc	$655,942	$232,269.42
Regents of the University of California, San Francisco	University of California, San Francisco School of Dentistry	San Francisco, CA	PreDoc	$87,739	$31,068.43
University of the Pacific	University of the Pacific Arthur A. Dugoni School of Dentistry	San Francisco, CA	PreDoc	$1,559,945	$552,377.38
Howard University	Howard University College of Dentistry	Washington, DC	PreDoc	$291,138	$103,092.13
Washington Hospital Center	Washington Hospital Center	Washington, DC	PostDoc	$155,105	$54,922.77
University of Miami	University of Miami Division of Oral and Maxillofacial Surgery	Miami, FL	PostDoc	$2,464,873	$872,812.88
Medical College of Georgia	Medical College of Georgia School of Dentistry	Augusta, GA	PreDoc	$596,298	$211,149.45
The Board of Trustees of the University of Illinois	University of Illinois at Chicago College of Dentistry	Chicago, IL	PostDoc	$259,801	$91,995.68
University of Kentucky Research Foundation	University of Kentucky College of Dentistry	Lexington, KY	PostDoc	$211,744	$74,978.67
University of Louisville Research Foundation	University of Louisville School of Dentistry	Louisville, KY	PreDoc	$978,044	$346,325.92
Louisiana State University Health Sciences Center New Orleans	Louisiana State University School of Dentistry	New Orleans, LA	PreDoc	$238,836	$84,571.96
Trustees of Boston University	Boston University Henry M. Goldman School of Dental Medicine	Boston, MA	PreDoc	$793,872	$281,110.51
Children's Hospital Corporation	Children's Hospital	Boston, MA	PostDoc	$2,200	$779.02
President and Fellows of Harvard College	Harvard School of Dental Medicine	Boston, MA	PreDoc	$4,108	$1,454.65
Tufts University	Tufts University School of Dental Medicine	Boston, MA	PreDoc	$81,195	$28,751.19
University of Maryland	University of Maryland Baltimore College of Dental Surgery	Baltimore, MD	PreDoc	$31,462	$11,140.71

University of Detroit Mercy	University of Detroit Mercy School of Dentistry	Detroit, MI	PreDoc	$334,090	$118,301.45
Minneapolis Medical Research Foundation	Minneapolis Medical Research Foundation/HCMC GPR Program	Minneapolis, MN	PostDoc	$259,674	$91,950.71
Truman Medical Center	Truman Medical Center, Incorporated	Kansas City, MO	PostDoc	$2,674	$946.86
University of North Carolina at Chapel Hill School of Dentistry	University of North Carolina at Chapel Hill School of Dentistry	Chapel Hill, NC	PostDoc	$25,117	$8,893.94
University of Nebraska Medical Center (UNMC)	Board of Regents of the University of Nebraska, UNMC	Omaha, NE	PostDoc	$36,517	$12,930.69
Center for Dentistry at Hackensack University Medical Center (HUMC)	Center for Dentistry at HUMC	Hackensack, NJ	PostDoc	$26,720	$9,461.57
St. Joseph's Hospital and Medical Center	St. Joseph's Hospital and Medical Center	Paterson, NJ	PostDoc	$40,412	$14,309.91
University of Medicine and Dentistry of New Jersey (UMDNJ) Medical School	UMDNJ New Jersey Dental School	Newark, NJ	PostDoc	$505,483	$178,991.81
Bronx-Lebanon Hospital Center	Bronx-Lebanon Hospital Center	Bronx, NY	PostDoc	$1,285,478	$455,188.47
The Trustees of Columbia University in the City of New York	Columbia University College of Dental Medicine	New York, NY	PreDoc	$306,458	$108,516.95
Erie County Medical Center Corporation	Erie County Medical Center Corp. Dept. of Dentistry	Buffalo, NY	PostDoc	$49,786	$17,629.25
Harlem Hospital Center	Harlem Hospital Center Department of Dentistry	New York, NY	PostDoc	$68,770	$24,351.49
Health and Hospitals Corp. (Jacobi Medical Center)	Health & Hospitals Corp./Jacobi Medical Center	Bronx, NY	PostDoc	$2,350,579	$832,341.31
Woodhull Medical Center	HHC/Woodhull Medical and Mental Health Center	Brooklyn, NY	PostDoc	$869,850	$308,014.36
Jamaica Hospital Medical Center	Jamaica Hospital Medical Center	Jamaica, NY	PostDoc	$607,196	$215,008.44
The New York City Health and Hospital Corporation Kings County Hospital Center	Kings County Hospital Center	Brooklyn, NY	PostDoc	$300,861	$106,535.05

Long Island Jewish Medical Center	Long Island Jewish Medical Center	New Hyde Park, NY	PostDoc	$48,337	$17,116.16
Lutheran Medical Center	Lutheran Medical Center	Brooklyn, NY	PostDoc	$2,348,895	$831,745.01
Montefiore Medical Center	Montefiore Medical Center	Bronx, NY	PostDoc	$852,260	$301,785.73
Mount Sinai School of Medicine	Mount Sinai School of Medicine	New York, NY	PostDoc	$393,430	$139,313.78
New York Hospital Medical Center, Queens	New York Hospital Queens	Flushing, NY	PostDoc	$233,048	$82,522.42
North Central Bronx Hospital	North Central Bronx Hospital	Bronx, NY	PostDoc	$345,230	$122,246.13
North Shore University Hospital	North Shore University Hospital	Manhasset, NY	PostDoc	$240,296	$85,088.95
Queens Hospital Center	Queens Hospital Center	Jamaica, NY	PostDoc	$73,287	$25,950.97
St. Barnabas Hospital	St. Barnabas Hospital	Bronx, NY	PostDoc	$406,641	$143,991.80
St. Luke's Roosevelt Institute for Health Sciences	St. Luke's-Roosevelt Institute for Health Sciences Center for Comprehensive Care	New York, NY	PostDoc	$1,411,493	$499,810.45
University of Rochester	Strong Memorial Hospital, Department of Dentistry	Rochester, NY	PostDoc	$52,216	$18,489.71
The Brooklyn Hospital Center	The Brooklyn Hospital Center	Brooklyn, NY	PostDoc	$154,755	$54,798.83
Westchester County Health Care Corporation	Westchester County Health Care Corporation	Valhalla, NY	PostDoc	$116,811	$41,362.84
Wyckoff Heights Medical Center	Wyckoff Heights Medical Center	Brooklyn, NY	PostDoc	$63,280	$22,407.47
Case Western Reserve University	Case Western Reserve University	Cleveland, OH	PostDoc	$50,610	$17,921.03
Lane Community College	Lane Community College	Eugene, OR	Hygiene	$191,591	$67,842.48
Oregon Health & Science University	Oregon Health & Science University	Portland, OR	PreDoc	$443,600	$157,079.00
Lehigh Valley Hospital and Health Network	Lehigh Valley Hospital, Inc.	Allentown, PA	PostDoc	$34,693	$12,284.81
Temple University of The Commonwealth System of Higher Education	The Maurice H. Kornberg School of Dentistry, Temple University	Philadelphia, PA	PreDoc	$223,205	$79,037.01
Trustees of the University of Pennsylvania	University of Pennsylvania School of Dental Medicine/ The Robert Schattner Center	Philadelphia, PA	PreDoc	$584,559	$206,992.66
Wellspan Health/George W. T. Bentzel Dental Center	Wellspan Health/George W.T. Bentzel Dental Center	York, PA	PostDoc	$15,327	$5,427.30

Texas A&M Health Science Center	Baylor College of Dentistry	Dallas, TX	PreDoc	$162,540	$57,555.50
University of Texas Health Science Center at San Antonio	University of Texas Health Science Center Dental School	San Antonio, TX	PostDoc	$125,688	$44,506.19
University of Utah	University of Utah	Salt Lake City, UT	PostDoc	$29,301	$10,375.50
			Total:	$25,524,815	$9,038,351.00

FY 2009 Community-Based Dental Partnership Program Awards

Loma Linda University School of Dentistry, CA: $320,000
University of Colorado Health Sciences Center, CO: $310,210
Nova Southeastern University, FL: $234,734
University of Illinois at Chicago, IL: $286,060
University of Louisville Research Foundation, KY: $359,568
Louisiana State University Health Sciences Center, School of Dentistry, LA: $373,192
Trustees of Boston University, MA: $300,000
University of Mississippi Medical Center, School of Dentistry, MS: $284,032
University of Medicine and Dentistry of New Jersey. NJ: $389,948
Lutheran Medical Center, NY: $244,604
The Trustees of Columbia University, NY: $396,971
Oregon Health & Science University, School of Dentistry, OR: $300,787

Dental Schools to Obtain Institutional Profile Numbers (IPF)

The American Association for Dental Research (AADR) has posted on its website information on how a dental school can obtain an Institutional Profile Number (IPF). During periods when the National Institutes of Health (NIH) limit the number of applications an institution can submit, a dental school with a unique IPF could submit its own applications (rather than submitting applications under the parent university), because the NIH defines “institution” as any entity having a unique Institution Profile Number (IPF). Currently, only one U.S. dental school holds an IPF (University of Medicine and Dentistry of New Jersey).

The number of dental schools without IPFs became apparent when institutions were competing for economic stimulus money, also known as the American Recovery and Reinvestment Act of 2009 (ARRA) funding. The National Institutes of Health (NIH) created guidelines through its National Center for Research Resources (NCRR) to administer the $1.3 billion allocated for “facilities infrastructure and shared instrumentation at universities and institutions.” The regulations limited the number of applications an institution can submit for grant programs to three per institution. A dental school had to compete with other schools within the parent institution for funds.

In order to avoid a circumstance like this in the future, an academic dental institution can apply for its own IPF number. For a detailed explanation of registering, please see the American Association for Dental Research’s article on IPFs at http://www.iadr.org/files/public/AADRGuidance_IPF.pdf.

U.S. Surgeon General Confirmed

The United States Senate has unanimously confirmed Dr. **Regina Benjamin** as the nation's Surgeon General. As such, she will oversee the Public Health Service and serve as a health advocate and educator.

Dr. Regina Benjamin was the founder and Chief Executive Officer of the Bayou La Batre Rural Health Clinic in Alabama and the Immediate Past Chair of the Federation of State Medical Boards of the United States, and she previously served as Associate Dean for Rural Health at the University of South Alabama College of Medicine. In 2002, as the President of the Medical Association of the State of Alabama, she became the first black woman to be president of a U.S. state medical society.

ADEA and AADR meet with NCRR

The American Dental Education Association (ADEA) and the American Association of Dental Research (AADR) met with NIH NCRR Director Dr. **Barbara Alving** to discuss infrastructure grants. The collaborative advocacy effort was an opportunity to address the dwindling research funding to dental schools. AADR Executive Director Dr. **Christopher Fox** encouraged Dr. Alving to explore ways of ensuring an equitable distribution of infrastructure funding among various scientific programs. Additionally, ADEA recommended dental representation on the NCRR Advisory Committee. The meeting was a first step in establishing communications with NCRR and providing the agency with insight on the needs of dental research institutions.

Call for Abstracts: National Oral Health Conference (NOHC)

The National Oral Health Conference program committee is seeking submissions for poster, roundtable, and oral presentations. The event theme is ***Pursuing Excellence in Dental Public Health,*** and the Committee is interested in scientific research, program evaluations, community-based interventions, and partnerships that relate to this topic. **Abstracts can be submitted online at www.nationaloralhealthconference.com (only one abstract will be accepted per presenter) and are due by December 21, 2009**. Applicants will be notified of selections in early February 2010. The conference will be held in April 26-28, 2010, at the Hilton Ballpark in St. Louis, Missouri. Sponsors of the event include the Association of State and Territorial Dental Directors, Academy of Public Health Dentists, and the U.S. Department of Health and Human Services Health Resources and Services Administration and Centers for Disease Control and Prevention. For questions, contact the NOHC office at 217-529-6503.

Marjorie McColl Petty of Delta Dental Appointed HHS Regional Director

On November 17, Secretary of Health and Human Services (HHS) **Kathleen Sebelius** announced that **Marjorie McColl Petty**, J.D., M.S., Chair of the Board of Directors of Delta Dental of Kansas, was among four health care professionals recently appointed to the positions of HHS Regional Directors.

Mrs. Petty has served on the Delta Dental board since 2001 and, as President of the Board from 2006 to 2008, granted $2.9 million for oral health projects for Kansans. She rounds out her public service with terms as Director of Public Affairs and Consumer Protection for the Kansas Corporation Commission (2003) and subcontractor for two HHS regional offices as Public Policy Manager. She will serve as Director of Region VI: Arkansas, Louisiana, New Mexico, Oklahoma, and Texas.

Dr. Kyu Rhee Named Chief Public Health Officer for HRSA

Kyu Rhee, M.D., MPP, FAAP, FACP, has accepted the post of Chief Public Health Officer for the Health Resources and Service Administration (HRSA). He will report directly to Dr. **Mary K. Wakefield**, HRSA Administrator. As Chief Public Health Officer, Dr. Rhee is positioned to reinvigorate a strong HRSA public health agenda, work at state and local levels to promote disease prevention and healthier living habits, and offer advice on community health issues.

Dr. Rhee's focus on working with low-income individuals and implementing policy to improve their care underscores a history of working in health care policy at the federal level. He recently served as Director of Office of Innovation and Program Coordination at the National Center on Minority Health and Health Disparities (NCMHD).

Dr. Rhee is board certified in pediatrics and internal medicine. He received his M.D. from the University of Southern California and a master's degree in Public Policy at the Harvard University John F. Kennedy School of Government. He is an Adjunct Professor at the George Washington University School of Public Health and serves on Roundtables in Literacy and Health Disparities, the American Medical Association's Commission to End Health Disparities, and the Editorial Board of the *Journal of Health Care for the Poor and Underserved.*

Funding Opportunities Update

www.GRANTS.gov

You must use www.GRANTS.gov to apply for a federal grant. The registration process can take up to one month. Assistance is available from www.Grants.gov help desk at support@grants.gov or 800-518-4726. To successfully register, it is necessary to do all of the following:

- Obtain an organizational Data Universal Number System (DUNS) number
- Register the organization with Central Contractor Registry (CCR)
- Identify the organization's E-Business Point of Contact (POC)
- Confirm the organization's CCR "Marketing Partner ID Number (M-PIN)" password
- Register an Authorized Organization Representative (AOR)

National Institutes of Health

- **Metagenomic Evaluation of Oral Polymicrobial Disease (R01),** (RFA-DE-10-003), National Institutes of Health, http://grants.nih.gov/grants/guide/rfa-files/RFA-DE-10-003.html

- **Ruth L. Kirschstein National Research Service Award (NRSA) Institutional Research Training Grants (T32),** (PA-10-036), National Institutes of Health, http://grants.nih.gov/grants/guide/pa-files/PA-10-036.html

- **Ruth L. Kirschstein National Research Service Award Short-Term Institutional Research Training Grants (T35),** (PA-10-037), National Institues of Health, http://grants.nih.gov/grants/guide/pa-files/PA-10-037.html

- **Transdisciplinary Research in Energetics and Cancer (U54),** (RFA-CA-10-006), National Institutes of Health, http://grants.nih.gov/grants/guide/rfa-files/RFA-CA-10-006.html

- **Epigenetic Approaches in Cancer Epidemiology (R01),** (PA-10-031), National Institutes of Health, http://grants.nih.gov/grants/guide/pa-files/PA-10-031.html

- **Prioritizing Molecular Targets for Cancer Prevention with Nutritional Combinations (R01),** (PA-10-035), National Institutes of Health, http://grants.nih.gov/grants/guide/pa-files/PA-10-035.html

- **Seek, Test, and Treat: Addressing HIV in the Criminal Justice System (R01),** (RFA-DA-10-017), National Institutes of Health, http://grants.nih.gov/grants/guide/rfa-files/RFA-DA-10-017.html

- **AIDS-Science Track Award for Research Transition (R03),** (PAR-10-021), National Institutes of Health, http://grants.nih.gov/grants/guide/pa-files/PAR-10-021.html

- **Paul B. Beeson Clinical Scientist Development Award in Aging (K08),** (RFA-AG-10-010), National Institutes of Health, http://grants.nih.gov/grants/guide/rfa-files/RFA-AG-10-010.html

- **Paul B. Beeson Patient-Oriented Research Career Development Award in Aging (K23),** (RFA-AG-10-011), National Institutes of Health, http://grants.nih.gov/grants/guide/rfa-files/RFA-AG-10-011.html

- **Engineered Nanomaterials: Linking Physical and Chemical Properties to Biology (U19),** (RFA-ES-09-011), National Institutes of Health, http://grants.nih.gov/grants/guide/rfa-files/RFA-ES-09-011.html

- **Limited Competition: NIH Competitive Revision Awards for Creating Virtual Consortium for Translational/Transdisciplinary Environmental Research (ViCTER) (R01),** (PAR-10-030), National Institutes of Health, http://grants.nih.gov/grants/guide/pa-files/PAR-10-030.html

- **Development, Application, and Evaluation of Prediction Models for Cancer Risk and Prognosis (R21),** (PA-10-026), National Institutes of Health, http://grants.nih.gov/grants/guide/pa-files/PA-10-026.html

- **Development, Application, and Evaluation of Prediction Models for Cancer Risk and Prognosis (R01),** (PA-10-025), National Institutes of Health, http://grants.nih.gov/grants/guide/pa-files/PA-10-025.html

- **State and Community Tobacco Control Policy and Media Research (U01),** (RFA-CA-10-008), National Institutes of Health, http://grants.nih.gov/grants/guide/rfa-files/RFA-CA-10-008.html

- **Engineered Nanomaterials: Linking Physical and Chemical Properties to Biology (U19),** (RFA-ES-09-011), National Institutes of Health, http://grants.nih.gov/grants/guide/rfa-files/RFA-ES-09-011.html

- **Technologies for Image-Guided Interventions (R01),** (RFA-EB-09-002), National Institutes of Health, http://grants.nih.gov/grants/guide/rfa-files/RFA-EB-09-002.html

- **Enabling Technologies in DNA Repair Research (R21),** (PAR-10-016), National Institutes of Health, http://grants.nih.gov/grants/guide/pa-files/PAR-10-016.html

- **Application and Early Stage Development of Emerging Technologies in Cancer Research (R21),** (RFA-CA-10-003), National Institutes of Health, http://grants.nih.gov/grants/guide/rfa-files/RFA-CA-10-003.html

- **Validation and Advanced Development of Emerging Technologies for Cancer Research (R33),** (RFA-CA-10-004), National Institutes of Health, http://grants.nih.gov/grants/guide/rfa-files/RFA-CA-10-004.html

Upcoming Meetings and Conferences

- **April 13-17, 2010, American Academy of Oral Medicine** will host its **64th Annual Meeting** with the theme "Oral Medicine and Immunity" at the Hyatt Regency Tamaya Resort and Spa in Santa Ana Pueblo, New Mexico. Early registration closes March 26, 2010. Please visit www.aaom.com/cde.cfm?event=225266 for registration information.

- **April 29-May 2, 2010, American Academy of Orofacial Pain** holds its **34th Scientific Meeting** at the newly renovated Disney World Contemporary Conference Center in Orlando, Florida. For meeting and registration information, please visit www.aaop.org/index.asp?Type=B_EV&SEC={A4704A5A-11E9-4719-B90A-5D4459C7211B}&DE={6F483C67-9E1B-4AE0-96B3-CABD446301C8}.

- **September 26-29, 2010, American Academy of Otolaryngology** holds its **2010 AAO-HNSF Annual Meeting and OTO Expo** at the Boston Convention and Exhibition Center, Boston, Massachusetts, expecting to draw almost 9,000 attendees and 300 exhibitors. Please see www.entnet.org/annual_meeting for more meeting information.

Quotable

"Without the watchful interference, the resolute interference, of government
There can be no fair play."
President Woodrow Wilson
The New Freedom, 1913

The ADEA Washington *Update* is published by the ADEA Center for Public Policy and Advocacy (ADEA CPPA) monthly when Congress is in session. Its purpose is to keep ADEA members abreast of federal issues and events of interest to the academic dental and research communities.

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1400 K Street, NW, Suite 1100, Washington, DC 20005
Telephone: 202-289-7201, Website: www.ADEA.org

Jack E. Bresch, Associate Executive Director and ADEA CPPA Director (BreschJ@ADEA.org)
Deborah Darcy, Director of Congressional Affairs (DarcyD@ADEA.org)
Monette D. McKinnon, Director of Legislative Policy Development (McKinnonM@ADEA.org)
Myla J. Moss, Director of Congressional Relations and Regulatory Affairs (MossM@ADEA.org)
Gregory Allen Stoute, D.M.D., M.P.H., 2009-10 ADEA/Sunstar Americas, Inc.
Harry W. Bruce, Jr. Legislative Fellow

HIPPA Breach Notification

October 19, 2009

Secretary Kathleen Sebelius
The Office for Civil Rights
U.S. Department of Health and Human Service
Attention: HITECH Breach Notification
Hubert H. Humphrey Building
Room 509F
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: Breach Notification for Unsecured Protected Health Information; Interim Final Rule

Dear Secretary Sebelius:

The American Dental Education Association ("ADEA") welcomes the opportunity to comment on the Department of Health and Human Service's ("Department") interim final rule on Breach Notification for Unsecured Protected Health Information, as published in the Federal Register on August 24, 2009 (the "Rule").[1]

ADEA represents all 59 dental schools in the United States, in addition to more than 700 dental residency training programs and nearly 600 allied dental programs as well as more than 12.000 faculty who educate and train the nearly 50,000 students and residents attending these institutions. It is at these academic dental institutions that future practitioners and researchers gain their knowledge, where the majority of dental research is conducted, and where significant dental care is provided. ADEA member institutions serve as dental homes for a broad array of racially and ethnically diverse patients, many of whom are uninsured, underinsured or rely on public programs such as Medicaid and the Children's Health Insurance Program. As dental educators and providers of oral health care services, ADEA members are committed to protecting the privacy of protected health information. ADEA appreciates HHS' efforts to implement the breach notification provisions of the Health Information Technology for Economic and Clinical Health ("HITECH") Act in a manner that is both protective of patient information yet workable for covered entities and their business associates.

I. Risk of Harm Standard

ADEA strongly supports HHS' adoption of a risk of harm standard as part of the definition of "breach" in the interim final regulations. A risk of harm standard is consistent with the Act's statutory language as well as with many state breach notification laws. This standard also is crucial to the effective implementation of the HITECH Act. We urge HHS to maintain this approach to the definition of breach in the final rule.

HHS' articulation of a risk of harm standard in the interim final regulations is consistent with the HITECH Act's statutory language. The HITECH Act's definition of "breach" clearly contemplates a determination of risk of harm to an individual. This definition – "the unauthorized acquisition, access, use, or disclosure of protected health information which compromises the security or privacy of such information . . ."[2] – requires a finding that the security or privacy of an individual's information was compromised before it can be determined that a breach has occurred. Where the security or privacy of an individual's information is not compromised by an acquisition, access, use or disclosure of that information, a breach has not occurred. HHS' standard also is consistent with state breach notification laws. Many states do not consider an unauthorized acquisition, access, use, or disclosure a breach if it poses no reasonable risk of harm. A risk of harm standard also is consistent with the approach taken in Federal requirements imposed on many federal agencies by OMB Memorandum M-07-16.[3]

ADEA also believes that a risk of harm approach is important to ensuring meaningful notice to patients when breaches have occurred. The fundamental justification for the required notification of a breach is to enable affected individuals to take precautions to

[1] 74 Fed. Reg. 42740 (August 24, 2009).
[2] HITECH Act, § 13400.
[3] *See* 74 Fed. Reg. 42740, 42744.

mitigate any harm that may arise from an unauthorized acquisition, access, use, or disclosure of their protected health information. Where there is not a significant risk of harm to the individuals, we believe there is little, if any, justification for requiring notification to individuals. Requiring notification in these circumstances would create a significant and unnecessary administrative burden and expense for the covered entity without providing meaningful protection to individuals. It also would create unwarranted concern among the affected individuals that could lead to them expending unnecessary time and money to try to address a privacy threat that likely does not exist.

ADEA appreciates that HHS' implementation of the breach notification regulations strikes a careful balance between creating a standard under which individuals are notified of breaches of their protected health information that pose a significant risk of harm and creating a standard that does not require over-notification of individuals in circumstances in which there is no significant likelihood of harm. We strongly support HHS' inclusion of a risk of harm standard in its interim final regulations and we urge the Department to maintain the standard in its final regulations.

II. Limited Data Sets

ADEA appreciates HHS' explanation that protected health information stripped of certain identifiers is exempt from the breach notification requirements. Specifically, HHS states that information from which the following information is removed cannot be subject to a breach: limited data set ("LDS") identifiers, date of birth, and zip code.[4] We agree that data in such form does not compromise the security or privacy of the protected health information and as such should not trigger breach notification requirements. Research is an important part of academic dental institutions' care mission, and dental school faculty are engaged in a broad range of oral, dental and craniofacial research. A risk of harm analysis for limited data sets that do contain date of birth and/or zip code allows a particular entity to determine whether or not re-identification of the data is likely, and thus whether the privacy and security of patients are compromised and a breach notification is required. We appreciate that HHS' interpretation avoids placing unnecessary administrative burdens upon covered entities. This is particularly important for smaller covered entities, such as dental school clinics.

III. Uses or Disclosures that Do Not Compromisethe Security or Privacy of PHI

ADEA respectfully requests that HHS reconsider its statement that "uses or disclosures of PHI that impermissibly involve more than the minimum necessary information, in violation of §§ 164.502(b) and 164.514(d), may qualify as breaches"[5] for purposes of the breach notification rule. We believe that situations in which a use or disclosure involves more than the minimum amount of information necessary to accomplish the use or disclosure largely would occur within a covered entity and a business associate. While the information disclosed may have been overbroad, the use or disclosure otherwise was in accordance with the HIPAA Privacy Rule.

A covered entity has a duty under the HIPAA Privacy Rule to mitigate any known harmful effect of a use or disclosure that does not adhere to the covered entity's policies and procedures and/or the HIPAA Privacy Rule. [6] Provided that a covered entity has fulfilled this duty to mitigate, it is not clear that there is a reasonable likelihood that the security or privacy of the information has been compromised or that affected individuals would receive any benefit from a breach notification related to this type of use or disclosure. Thus, we urge HHS to reevaluate its position that uses or disclosures of PHI that involve more than the minimum necessary information may qualify as breaches for purposes of the breach notification rule and instead consider that these uses and disclosures may already appropriately be handled under the Privacy Rule.

IV. Exceptions to the Definition of "Breach"

ADEA supports the workability of the implementation approach HHS has taken with respect to the exceptions to the definition of breach. HHS' approach in the Rule acknowledges the HIPAA Privacy and Security Rules' requirements for covered entities, such as dental schools, while at the same time permitting the internal uses and disclosures of PHI that are crucial to quality patient care and provider education. We support HHS' application of the exceptions to workforce members and organized healthcare arrangements, which provides covered entities with guidance critical to compliance with the breach notification regulations.[7] ADEA further appreciates HHS' interpretation of the exception regarding further use and disclosure of information inadvertently obtained as encompassing situations in which a recipient does not further use or disclose the information in a manner not permitted under the HIPAA Privacy Rule.[8]

ADEA further appreciates HHS' explanation that, for purposes of the statutory breach definition exception for inadvertent disclosures by a person who is otherwise authorized to access PHI at a facility operated by a covered entity or business associate to another similarly situated individual at the same facility,[9] the same legal entity or status of entities as an organized health care arrangement constitutes the same facility. ADEA believes this interpretation appropriately recognizes the realities of academic dental institutions which may operate clinics in locations separate from the campus where the school is located.

V. Notification of a Breach by a Business Associate to a Covered Entity

ADEA is concerned by HHS' statement that a business associate may sometimes be an "agent" of a covered entity, and, if so, the business associate's knowledge of a breach will be imputed to the covered entity for purposes of establishing when a breach was

[4] *See* 45 C.F.R. § 164.402.
[5] 74 Fed. Reg. 42746.
[6] 45 C.F.R. § 164.530(f).
[7] 74 Fed. Reg. 42747.
[8] 74 Fed. Reg. 42747; 45 C.F.R. § 164.402(2)(i).
[9] HITECH Act § 13400(1)(B)(ii), (iii).

discovered.[10] Because HHS states that "the federal common law of agency is to control in determining who is an agent of the covered entity,"[11] the agency determination likely will create a great deal of confusion. Agency law is largely state-specific and federal common law on agency demands a specific facts and circumstances analysis for each determination and can lead to differing conclusions depending upon who is analyzing the facts.

According to the Restatement of Agency, an entity (in this case, a business associate) is an agent rather than an independent contractor of another entity (here, the covered entity) only in limited situations. A business associate may be an agent of the covered entity if the business associate has a fiduciary obligation to the covered entity, is acting on behalf of the covered entity, and is acting in the covered entity's interest rather than its own interest. Small covered entities such as dental school clinics will likely find such a fact-specific determination unfeasible to undertake in every instance.

Unlike HHS' proposed standard, other relevant regulations utilize a different method for addressing the covered entity-business associate agency question. For example, the HIPAA Enforcement Rule does not require an agency determination for business associates for enforcement and liability purposes; it instead includes a business associate exception to the liability rules.[12] Under this exception, where a covered entity meets all of HIPAA's privacy and security requirements with regard to business associates, the covered entity is not required to make a determination of whether its business associates are its agents under common law. We urge HHS to utilize a similar approach in its breach notification rules. If HHS requires covered entities to determine whether each of their business associates is an agent, it will impose a tremendous administrative and analytical burden on those covered entities and will be inconsistent with other HHS guidance.

We urge HHS to make clear that knowledge of a breach that occurs at a business associate is not imputed to a covered entity where the business associate is an agent and that the timeframe in which a covered entity must provide notification of such a breach does not depend upon a determination of agency. Instead, a covered entity's discovery of a breach occurs when the covered entity first learns of the breach from the business associate, pursuant to the timeframe in which business associates must report breaches to covered entities under 45 C.F.R. 164.410(a).

VI. Annual Breach Logs – Uniform Submission Date

ADEA supports HHS' choice of a uniform date for submission of annual logs of breaches affecting fewer than 500 individuals. The choice of a designated date rather than different dates for each entity ensures that entities required to submit annual breach logs will face less confusion and difficulty with compliance than they would without the uniform deadline of 60 days after the end of the calendar year. We encourage HHS to revisit the form provided on its web site for reporting of such breaches, as the form currently does not appear to allow for a covered entity to actually submit a breach log, but instead requires separate input of each breach in a manner that does not appear to facilitate annual reporting.

VII. Clarification of the Relationship to State Laws

ADEA appreciates HHS' determination that the breach notification required under federal law may also include information in addition to the information required by federal law and regulations. With this clarification, HHS allows entities to satisfy both federal and state breach notification requirements in one communication to affected individuals in most cases. Meeting both sets of requirements in one communication reduces the administrative burdens on covered entities as well as prevents confusion among affected individuals who might otherwise receive more than one notice for a single breach.

ADEA also appreciates HHS' explanation that the federal breach notification laws preempt contrary state laws. Consistency of application is important to accurate implementation of the statute, and we appreciate that this clarification will enable us to do so.

VIII. Conclusion

Thank you, Madame Secretary, for the opportunity to comment on the interim final rule and its implementation of the HITECH data breach provisions. ADEA acknowledges the importance of protecting the privacy of patient information and supports the implementation of safeguards designed to prevent misuse of such information. We hope HHS will continue to take the necessary measures to ensure that the framework for protecting privacy is one that allows the continuation of quality patient care and that recognizes the unique needs of academic dental institutions and patient care.

If you have any questions about these comments, please contact Jack Bresch, Associate Executive Director and Director of the ADEA Center for Public Policy and Advocacy at 202/289-7201 or at breschj@adea.org.

Sincerely,

/signed/

Richard W. Valachovic, D.M.D., M.P.H.
Executive Director

[10] 74 Fed. Reg. 42754.
[11] *Id.*
[12] 45 C.F.R. § 160.402(c).