

DEPARTMENT of HEALTH and HUMAN SERVICES

Fiscal Year

2017

Office for Civil Rights

Justification of Estimates for Appropriations Committee



I am pleased to present the Office for Civil Rights (OCR) Fiscal Year 2017 Congressional Justification. This budget supports the President's and Secretary's priority initiatives and reflects the goals and objectives of the Department.

OCR's request provides the requisite resources to protect the public's right to equal access and opportunity to participate in and receive services from all Department of Health and Human Services' (HHS) programs without facing unlawful discrimination, and to protect the privacy and security of individually identifiable health information from unauthorized disclosure. The budget request also funds three initiatives:

- Audit Program: A Health Insurance Portability and Accountability Act (HIPAA) privacy, security, and breach notification rule audit program as mandated within the Health Information Technology for Economic and Clinical Health (HITECH) Act. The audit program would add value to OCR's compliance and enforcement mission by proactively and systematically measuring industry compliance with HIPAA requirements.
- Section 1557 Enforcement: Section 1557 of the Affordable Care Act (ACA) is transformative because it extends statutory protections against sex discrimination to the health care context for the first time. As a result of the new law and corresponding regulation, complex cases that involve novel issues of law and complicated facts will dramatically increase. To handle this considerable mission expansion, OCR will ramp up its investigative staff.
- Modernizing HIPAA and Supporting Innovation in Healthcare: Since the issuance of the HIPAA rules, there have been significant advances and innovations in health information technology, health delivery systems, and health research. This initiative will focus efforts to modernize the health information privacy and security protections paradigm, while enabling further advances in health care, research, and technology that will improve health outcomes and improve ability to detect and prevent cyber-attacks. This initiative also encompasses efforts to streamline HIPAA requirements to make them less burdensome while at the same time ensuring robust enforcement as well as to evaluate new areas where HIPAA does not currently apply.

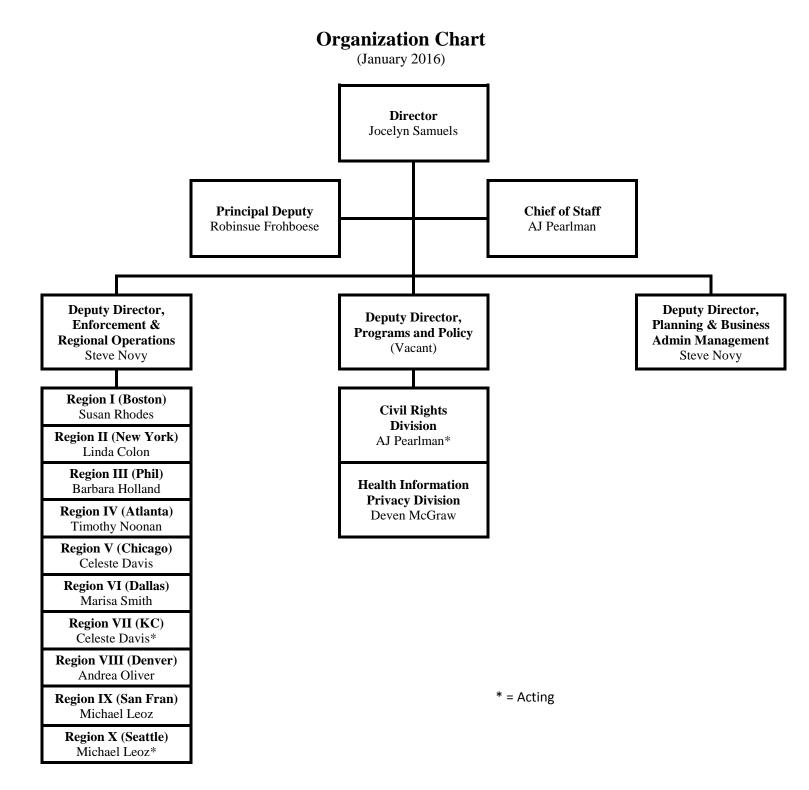
OCR continues to explore all means to improve operations via the implementation of critical initiatives and through improvement and strengthening of our staff expertise, automated systems, and core processes. We understand that the American people greatly value their civil rights and their right to healthcare privacy and OCR is committed to continued vigorous enforcement of the laws to protect those rights.

Jocelyn Samuels Director, Office for Civil Rights

Office for Civil Rights

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Organizational Chart: Text Version

Office for Civil Rights

- Director Jocelyn Samuels
- Chief of Staff AJ Pearlman

The following offices report directly to the Director:

- Acting Deputy Director, Enforcement and Regional Operations
 - Steve Novy
- Deputy Director, Programs and Policy
 - Vacant
- Deputy Director, Planning and Business Administration Management
 - Steve Novy

The following regional managers report to the Deputy Director, Enforcement and Regional Operations:

- Susan Rhodes, Boston Regional Office
- Linda Colon, New York Regional Office
- Barbara Holland, Philadelphia Regional Office
- Timothy Noonan, Atlanta Regional Office
- Celeste Davis, Chicago Regional Office
- Marisa Smith, Dallas Regional Office
- Celeste Davis (Acting), Kansas City Regional Office
- Andrea Oliver, Denver Regional Office
- Michael Leoz, San Francisco Regional Office
- Michael Leoz (Acting), Seattle Regional Office

The following offices report to the Deputy Director of Programs and Policy:

- Civil Rights Division
 - o AJ Pearlman (Acting)
- Health Information Privacy Division
 - o Deven McGraw

Introduction and Mission

The Office for Civil Rights (OCR), a staff division of the U.S. Department of Health and Human Services (HHS), ensures that individuals receiving services from HHS-funded programs are not subject to unlawful discrimination and that the privacy and security of individuals' health information is protected. By removing discriminatory barriers to HHS-funded services, OCR carries out the HHS mission of improving the health and well-being of all Americans and providing essential human services, especially for those who are least able to help themselves. By protecting the privacy and security of health information, OCR helps to advance consumer involvement in health care decision-making and to assist in delivery system reform, both of which promote better health outcomes for the nation.

Mission

Through investigations, technical assistance, voluntary compliance efforts, enforcement, policy development, and education, OCR ensures that all people have access to health care and services without discrimination and protects the privacy and security of individuals' health information by:

- Ensuring that recipients of HHS federal financial assistance comply with federal civil rights laws
 that prohibit discrimination on the basis of race, color, national origin (including limited English
 proficiency), disability, age, sex (including gender identity) and religion.
- Enforcing provisions of the Affordable Care Act (ACA) that prohibit discrimination in health care programs and activities that are integral to expanding access to health coverage and care, advancing health equity, and reducing health disparities.
- Ensuring the practices of health care providers, health plans, healthcare clearinghouses, and
 their business associates adhere to Federal privacy, security, and breach notification regulations
 under the Health Insurance Portability and Accountability Act (HIPAA) through the investigation
 of citizen complaints, self-reports of breaches, compliance reviews, and audits.
- Leading interagency efforts to ensure comprehensive privacy and security protections for individuals' personal health information when shared to promote medical discoveries or through emerging technologies.
- Enforcing privacy protections under the Genetic Information Nondiscrimination Act and the confidentiality provisions of the Patient Safety and Quality Improvement Act.

Vision

Through enforcement of laws prohibiting discrimination and protecting the rights of individuals to the privacy and security of their health information, the OCR helps to ensure equal access to health and human services, advance the health and well-being of members of vulnerable communities, protect individuals' private health information, and provide the tools for full consumer engagement in decisions related to their health care.

Overview of Budget Request

OCR's FY 2017 budget request of \$42,705,000 represents a \$3.907 million increase over the FY 2016 Enacted Level.

The request supports OCR's essential programmatic focus as the primary defender of the public's right to nondiscriminatory access to and receipt of Federally funded health and human services, and privacy and security protections for individually identifiable health information.

Program increases:

<u>Audit Program (+1.500M):</u> The increase funds an initiative for a Health Insurance Portability and Accountability Act (HIPAA) Privacy, Security, and Breach Notification Rule Audit Program as mandated by Section 13411 of the HITECH Act. The audit program would add value to OCR's compliance and enforcement mission by proactively and systematically measuring industry compliance with HIPAA privacy and security requirements.

<u>Section 1557 Enforcement (+1.361M):</u> Section 1557 of the Affordable Care Act (ACA) is transformative because it extends protections against sex discrimination to the health care context for the first time. As a result of the new law and corresponding regulation, complex cases that involve novel issues of law and complicated facts will dramatically increase. To handle this considerable increase in workload, OCR will ramp up its investigative staff.

Modernizing Health Insurance Portability and Accountability Act in Supporting Innovation in Healthcare (+1.046M): Since the issuance of the HIPAA rules, there have been significant advances and innovations in health information technology, health delivery systems, and health research. This initiative will focus efforts to modernize the health information privacy and security protections paradigm, while enabling further advances in health care, research, and technology that will improve health outcomes and improve ability to detect and prevent cyber-attacks. This initiative also encompasses efforts to streamline HIPAA requirements to make them less burdensome while at the same time ensuring robust enforcement as well as to evaluate new areas where HIPAA does not currently apply.

Overview of Performance

OCR's overarching goals encompass multiple supporting objectives that align with the Department's Strategic Plan:

	OCR Goal	OCR Supporting Objectives	HHS Goal/Objectives
1.	Raise awareness, increase understanding, and ensure compliance with all federal laws requiring non-discriminatory access to HHS funded programs and protect the privacy and security of personal health information	 A. Increase access to and receipt of non-discriminatory quality health and human services while protecting the integrity of HHS federal financial assistance B. Protect the privacy and security of personally identifiable health information for healthcare consumers (HIPAA rule activities and enforcement) C. Provide information, public education activities, and training to representatives of health and human service providers, other interest groups, and consumers (civil rights and health information privacy mission activities) D. Increase the number of covered entities that take corrective action, including making substantive policy changes or developing new policies as a result of review and/or intervention 	#1 E , #3 A,C #1 E,F #1 E , #3 B
2.	Enhance operational efficiency	 A. Maximize efficiency of operations by streamlining processes and the optimal allocation of resources B. Improve financial management and the integration of budget and performance data (Increase resource management process oversight, strengthen internal controls, maintain viable performance objectives) C. Advance human capital management (Provide training, develop and mentor subordinates, promote effectiveness) 	#4 A #4 A #4 C

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The following Outputs and Outcomes Table presents the current OCR performance measures¹ and results along with the proposed FY 2017 targets:

Program/Measure	Year and Most Recent Result / Target for Most Recent Result / (Summary of Result)	FY 2016 Target	FY 2017 Target	FY 2017 Target +/- FY 2016 Target
1.1.1 The number of covered entities taking	FY 2015: 2,983			
corrective actions as a result of OCR	Target: 5,900	5,900	3,000	-2,900
intervention per year (Outcome)	(Target Not Met)			
1.1.2 The number of Covered Entities	FY 2015: 2055			
making substantive policy changes as a	Target: 1,000	750	750	Maintain
result of OCR intervention/year (Outcome)	(Target Exceeded)			
1.1.3A Percent of closure for civil rights cases/ cases received each year (Outcome) ²	FY 2015: 94% Target: 90% (Target Exceeded)	90%	90%	Maintain
1.1.3B Percent of closure for health information privacy cases/cases received each year (Outcome)	FY 2015: 90% Target: 66% (Target Exceeded)	75%	80%	+5%
1.1.3C Percent of closure for Medicare application review/reviews received each year (Output) ³	FY 2015:100% Target: 90% (Target Exceeded)	90%	90%	Maintain
1.1.4 Percent of civil rights cases and	FY 2015: 96%	92%	020/	Maintain
Medicare application reviews resolved per received per year. (Outcome)	Target: 92% (Target Exceeded)	92%	92%	Maintain
1.1.6 Number of individuals whom OCR	FY 2015: 2,269,126			
provides information and training annually (Output) ³	Target: 3,263,000 (Target Not Met)	3,426,000	3,426,000	Maintain
1.1.7 Percent of civil rights complaints requiring formal investigation resolved within 365 days (Output)	FY 2015: 35% Target: 41% (Target Not Met)	41%	41%	Maintain
1.1.8 Percentage of civil rights complaints not requiring formal investigation resolved within 180 days (Output)	FY 2015: 89% Target: 80% (Target Exceeded)	80%	95%	+15%
1.1.9 Percentage of health information privacy complaints requiring formal investigation resolved within 365 days (Output)	FY 2015: 70% Target: 68% (Target Exceeded)	68%	68%	Maintain
1.1.10 Percentage of health information privacy complaints not requiring formal investigation resolved within 180 days (Output)	FY 2015: 97% Target: 72% (Target Exceeded)	75%	95%	+20%

 $^{^{\}mathrm{1}}$ OCR has intitiated a comprehensive review of its performance measures and targets

² 1.1.3 Percentage of closure for civil rights cases, health information privacy cases, and Medicare reviews/ cases and reviews received" is now captured as 1.1.3 A, B, and C. 1.1.5 "Percentage of privacy cases resolved per cases received" was eliminated as the data is captured in 1.1.3 B.

³ FY15 and forward targets for 1.1.6 were adjusted upward to account for the change in methodology for calculating this measure. Beginning in FY 2014, this measure included the number of times the OCR website is viewed

In FY 2015, OCR met its productivity and closure targets by closing a high percentage of cases nearly equivalent to all cases received in the year. (Measure 1.1.3A, Target: 90%, FY15 Actual: 94% and Measure 1.1.3B, Target: 66%, FY15 Actual: 90%). The total number of cases resolved in this time period including health information privacy cases, civil rights cases, and civil rights clearances reached 22,843 which represents the highest case resolution productivity in OCR's history. A major part of OCR's success in this area is the full implementation of OCR's Centralized Case Management Operations (CCMO) in FY 2015. The CCMO handles all incoming complaints to OCR by assessing which cases can be closed administratively and which will be transferred to an OCR regional office for further review or investigation. These numbers represent significant achievements considering the rise in cases in a flat budget environment .

Regarding investigated complaints resulting in corrective action, OCR did not meet its target for this performance objective (Measure 1.1.1, Target: 5,800 cases closed with corrective action, FY15 Actual: 2,983). This measure is no longer a realistic measure of OCR's work as OCR conducts fewer routine investigations per year so that it can focus on larger, more complex work which impacts a broader audience. In FY 2015, OCR completed 3,972 investigations (including civil rights clearances); therefore the target of 5,800 as closed with corrective action is not a feasible target considering its actual investigated workload. However, OCR continues to effectuate corrective action in other ways. A large number of complaints are resolved by OCR through the provision of technical assistance to the named entity without a formal investigation. These cases involve simple issues that, if substantiated, could easily be addressed by the entity with voluntary corrective action. The use of technical assistance to resolve these types of complaints is an efficient way for OCR to use its resources by notifying its regulated community about potential compliance deficiencies and requesting the entity to take any necessary voluntary corrective action.

OCR exceeded its target for resolving its most complex Health Information Privacy (HIP) cases requiring formal investigation within 365 days (1.1.9, Target: 68%, FY15 Actual: 70%). On the Civil Rights side, the organization continued to struggle to meet this target of closing out its most complex civil rights enforcement work within a 365 day timeframe (Measure 1.1.7, Target 41%, FY15 Actual: 35%). Civil Rights cases tend to be more complex and involve more resources to investigate which, when combined with other priorities in the region, can stretch the closure of a case beyond 365 days. Further, OCR initiated a civil rights backlog case reduction project in FY 2015 which pushed OCR's regional offices to better manage its civil rights caseload and provided the regions tools and guidance to close older cases. While these efforts were successful at closing out older civil rights cases, this success increased the overall age of investigated civil rights closures and hence made this measure more difficult to meet.

In terms of management of administrative closures that will not lead to an investigation, OCR has achieved significant and sustained success in two of its primary measures on timeliness (Measure 1.1.8, Target: 80%, FY 2015 Actual: 89% and Measure 1.1.10, Target: 72%, FY15 Actual: 97%). This success has been achieved through the full implementation of CCMO in FY 2015 to intake, assess, and process administrative closures upon receipt.

Outreach is critical to the OCR mission as it helps OCR's regulated community understand its obligations. It also helps to educate consumers about their civil rights and health information privacy rights. OCR was able to reach 2,269,126 individuals with information and training in FY 2015. Much of the decline in the FY 2015 numbers relates to not recertifing additional Medscape modules in FY 2015 resources

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toward promotion of videos, digital media, or other outreach activities as we have in the past. A large part of the recurring exposure was due to the OCR website, which has consistently demonstrated its popularity and ability to reach a large number of users from the public and the regulated community.

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All Purpose Table (Dollars in Thousands)

Program	FY 2015 Final	FY 2016 Enacted	FY 2017 President's Budget	FY 2016 (+/-) FY 2015
Enforcement and Regional Operations	25,091	25,865	28,029	+2,164
Programs and Policy	7,899	7,453	9,196	+1,743
Planning and Business Administration Management	5,808	5,480	5,480	-
Total, Office for Civil Rights	38,798	38,798	42,705	+3,907
FTE	167	179	197	+18

Office for Civil rights

Appropriations Language

For expenses necessary for the Office for Civil Rights, [\$38,798,000] \$42,705,000.

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Amounts Available for Obligation (Dollars in Thousands)

Detail	FY 2015 Actual	FY 2016 Enacted	FY 2017 President's Budget
Annual appropriation	38,798	38,798	42,705
Rescission	-	-	-
Transfers	-	-	-
Subtotal, adjusted budget authority	38,798	38,798	42,705
Unobligated balance lapsing	-176	-	-
Total Obligations	38,622	38,798	42,705

Summary of Changes (Dollars in Thousands)

Budget Year and Type of Authority	Dollars	FTE
FY 2016 Enacted	38,798	177
FY 2017 Estimated Budget Authority	42,705	195
Net Changes	+3,907	+18

Program Increases	FY 2017 PB FTE	FY 2017 PB BA	FY 2017 +/- FY 2016 FTE	FY 2017 +/- FY 2016 BA
Full-time permanent	195	18,807	+18	+2,075
Other than full-time permanent	-	711	-	+9
Other personnel compensation	-	331	-	+35
Military personnel	2	161	-	+2
Civilian benefits	-	6,361	-	+671
Military benefits	-	80	-	+2
Benefits to former personnel	-	31	-	-
Travel and transportation of persons	-	492	-	+143
Communication, utilities, and miscellaneous charges	-	219	-	+15
Printing and reproduction	-	123	-	+63
Other services	-	1,326	-	+1,213
Operation and maintenance of facilities	-	440	-	+93
Operation and maintenance of equipment	-	405	-	+18
Supplies and materials	-	199	-	+8
Equipment	-	30	-	-
Total Increases	197	29,726	+18	+4,347

Program Decreases	FY 2017 PB FTE	FY 2017 PB BA	FY 2017 +/- FY 2016 FTE	FY 2017 +/- FY 2016 BA
Rental payments to GSA	-	3,092	-	-220
Purchase of goods and services from Government accounts	-	9,887	-	-220
Total Decreases	-	12,979	-	-440

Total Changes	FY 2017 PB FTE	FY 2017 PB BA	FY 2017 +/- FY 2016 FTE	FY 2017 +/- FY 2016 BA
Total Increases	-	-	+18	+4,701
Total Decreases	-	-	-	-440
Total Net Change	197	42,705	+18	3,907

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Budget Authority by Activity (Dollars in Thousands)

Activity	FY 2015 FTE	FY 2015 Actual	FY 2016 FTE	FY 2016 Enacted	FY 2017 FTE	FY 2017 President's Budget
Enforcement and Regional Operations	108	25,091	118	25,865	128	28,029
Programs and Policy	34	7,899	34	7,453	42	9,196
Planning and Business Administration						
Management	25	5,808	27	5,480	27	5,480
Total, Budget Authority	167	38,798	179	38,798	197	42,705

Authorizing Legislation

(Dollars in Thousands)

Authorizing Legislation	FY 2016 Amount Authorized	FY 2016 Appropriations Act	FY 2017 Amount Authorized	FY 2017 President's Budget
Office for Civil Rights	Indefinite	\$38,798	Indefinite	\$42,705
Grand Total Appropriation	-	\$38,798	-	\$42,705

OCR Legal Authorities

- Social Security Act of 1934, Section 508 (Public Law 74-271) (42 USC 708)
- Public Health Service Act of 1944, Titles VI, Title XVI, Section 533, Section 542, Section 794, Section 855, Section 1908, Section 1947, as amended (42 USC 291 et seq, 42 USC 300 et seq, 42 USC 290dd-1, 42 USC 295m and 296g, 42 USC 300w-7, 43 USC 290cc-33, 43 USC 300x-57)
- Civil Rights Act of 1964, Title VI, as amended (Public Law 88-352) (42 USC 2000d et seq)
- Treatment and Rehabilitation Act of 1970 (Public Law 91-616)
- Comprehensive Health Manpower Training Act of 1971 (Public Law 92-157)
- Nurse Training Act of 1971 (Public Law 92-158)
- Drug Abuse Offense and Treatment Act of 1972 (Public Law 92-255)
- Education Amendments of 1972, Title IX, as amended (Public Law 92-318) (20 USC 1681)
- Rehabilitation Act of 1973, Section 504, Section 508, as amended (Public Law 93-112) (29 USC 794)
- Comprehensive Alcohol Abuse & Alcoholism Prevention, Treatment, and Rehabilitation Act Amendments of 1974 (Public Law 93-282)
- The Church Amendments (42 USC 300a-7)
- National Research Service Award Act of 1974 (Public Law 93-348)
- Health Care Professions Educational Assist Act of 1974 (Public Law 94-484)
- Age discrimination Act of 1975, Sections 301-8, as amended (Public Law 94-135) (42 USC 6101 et seq)
- Public Telecommunications Financing Act of 1978, Section 395 (Public Law 95-567)
- Omnibus Reconciliation Act of 1981 (Public Law 97-35)
- Americans with Disabilities Act of 1990, Title II (Public Law 101-336) (42 USC 12131)
- Improving America's Schools Act of 1994, Subpart E (Public Law 103-382)
- Small Business Job Protection Act of 1996, Sections 1807/1808c (Public Law 104-188) (42 USC 1996b)
- Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191)
- Patient Safety and Quality Improvement Act of 2005 (Public Law 109-41)
- Genetic Information Nondiscrimination Act of 2008 (Public Law 110-233)
- Health Information Technology for Economic and Clinical Health (HITECH) Act, American Recovery and Reinvestment Act of 2009 (Public Law 111-5)
- Patient Protection and Affordable Care Act of 2010, Sections 1303(b)(4), 1553, and 1557 (Public Law 111-148, as amended by Public Law 111-152)
- Consolidated Appropriations Act, 2016, Pub. L. No. 114-113, Div. H, Sec. 507 (Dec. 18, 2015)

Appropriations History

Details	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriations
2008	-	-	-	-
Appropriation	-	-	-	-
Base	33,748,000	33,748,000	33,748,000	31,628,000
Rescission (PL 110-161)				(553,000)
Subtotal	33,748,000	33,748,000	33,748,000	31,075,000
Trust Funds	-	-	-	-
Base	3,314,000	3,314,000	3,314,000	3,314,000
Rescission (PL 110-161)	-	-	-	(57,000)
Subtotal	3,314,000	3,314,000	3,314,000	3,257,000
2009	-	-	-	-
Appropriation	-	-	-	-
Base	36,785,000	36,785,000	36,785,000	36,785,000
Subtotal	36,785,000	36,785,000	36,785,000	36,785,000
Trust Funds	-	-	-	-
Base	3,314,000	3,314,000	3,314,000	3,314,000
Subtotal	3,314,000	3,314,000	3,314,000	3,314,000
2010	-	-	-	-
Appropriation	-	-	-	-
Base	37,785,000	37,785,000	37,785,000	37,785,000
Rescission (PL 111-117)				(6,000)
Subtotal	37,785,000	37,785,000	37,785,000	37,779,000
Trust Funds	-	-	-	-
Base	3,314,000	3,314,000	3,314,000	3,314,000
Subtotal	3,314,000	3,314,000	3,314,000	3,314,000
2011	-	-	-	-
Appropriation	-	-	-	-
Base	44,382,000	44,382,000	44,382,000	37,785,000
Rescission (PL 112-10)	-	-	-	(76,000)
Subtotal	44,382,000	44,382,000	44,382,000	37,709,000
Trust Funds	-	-	-	-
Base	3,314,000	3,314,000	3,314,000	3,314,000
Rescission (PL 112-10)	-	-	-	(7,000)
Subtotal	3,314,000	3,314,000	3,314,000	3,307,000
2012	-	-	-	-
Appropriation	-	-	-	-
Base	44,382,000	41,016,000	41,016,000	41,016,000
Rescission (PL 112-74)	-	-	-	(78,000)
Subtotal	44,382,000	41,016,000	41,016,000	40,938,000

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Appropriations History (Continued)

Details	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriations
2013	-	-	-	-
Appropriation	-	-	-	-
Base	38,966,000	-	38,966,000	40,938,000
Sequestration	-	-	-	(2,059,000)
Rescission (PL 113-6)	-	-	-	(82,000)
Transfers (PL 112-74)	-	-	-	(182,000)
Subtotal	38,966,000		38,966,000	38,615,000
2014	-	-	-	-
Appropriation	-	-	-	-
Base	42,205,000	-	42,205,000	38,798,000
Subtotal	42,205,000	-	42,205,000	38,798,000
2015	-	-	-	-
Appropriation	-	-	-	-
Base	41,205,000	-	38,798,000	38,798,000
Subtotal	41,205,000	-	38,798,000	38,798,000
2016	-	-	-	-
Appropriation	-	-	-	-
Base	42,705,000	-	38,798,000	38,798,000
Subtotal	42,705,000	-	38,798,000	38,798,000
2017	-	-	-	-
Appropriation	-	-	-	-
Base	42,705,000	-	-	-
Subtotal	42,705,000	-	-	-

Summary of the Request

The U.S. Department of Health and Human Services (HHS) Office for Civil Rights (OCR) is the primary defender of the public's right to privacy and security of protected health information and non-discriminatory access to Federally-funded health and human services. Through prevention and elimination of unlawful discrimination and by protecting the privacy and security of individually identifiable health information, OCR helps HHS carry out its overall mission of improving the health and well-being of all people affected by the Department's many programs. To most effectively accomplish this enormously important undertaking, OCR actively partners with government and private sector entities at the local, state, and national levels.

For FY 2017, OCR requests \$42,705,000, an increase of \$3,907,000 from the FY16 Enacted Level to fund its nation-wide health care anti-discrimination and health information privacy and security mission performed and supported by OCR's three activities.

- \$28,029,000 for Enforcement and Regional Operations an increase of \$2,164,000
- \$9,196,000 for Programs and Policy an increase of \$1,743,000
- \$5,480,000 for Planning and Business Administration Management

Enforcement and Regional Operations

(Dollars in Thousands)

Program	FY 2015 Final	FY 2016 Enacted	FY 2017 President's Budget	FY 2017 +/- FY 2016
Budget Authority	25,091	25,865	28,029	+2,164
FTE	108	118	128	+10

Program Description

Enforcement and Regional Operations (ERO) is charged with prevention and elimination of unlawful discrimination and the protection of privacy and security of individually identifiable health information through enforcement activities under the laws within OCR's jurisdiction. The personnel based in OCR's regional offices are at the forefront of OCR's enforcement efforts and are responsible for performing investigations of alleged violations of civil rights and health information privacy and security laws, responding to inquiries and requests from covered entities and other healthcare organizations, and conducting outreach and education. Regions are led by Regional Managers who report to the Deputy Director and are responsible for all operations within their regions.

Over the past several years, the CCMO has become a key organization within ERO. First implemented in FY 2012 and fully operational in FY 2014, CCMO consists of two units, the Customer Response Center (CRC) and the Central Intake Unit (CIU), and reflects a dramatic shift in OCR's core case management process. In FY 2015, the CRC handled 27,120 calls. CRC staff respond to inquiries from all sources (phone, mail, fax, and web) and educate individuals who contact OCR on individuals' rights and covered entities' responsibilities under both HIPAA and the civil rights laws under OCR's jurisdiction. OCR provides interpreter services in seven different languages to assist with the intake of complaints from individuals who are limited English proficient, as well as technical assistance and early intervention to facilitate prompt resolution of pressing situations, such as assisting an individual in obtaining their medical record or the use of a sign language interpreter. This centralization is much easier for users to access, more efficient for OCR to operate, and has significantly assisted OCR's regional offices in being able to focus instead on case investigation, compliance reviews, the development of high impact resolutions, and outreach.

ERO also oversees national civil rights corporate agreements in OCR's nationwide civil rights pre-grant review program for health care providers applying to participate in the Medicare program. Through this initiative, OCR enters into civil rights corporate agreements with major health care corporations to develop model civil rights policies and procedures at all facilities under corporate ownership and control, extending their reach to facilities beyond the scope of Medicare Part A program requirements. In this way, OCR is achieving voluntary compliance with health care organizations on a large scale, thus maximizing its impact and civil rights compliance efforts within the Medicare provider community.

Over the past several fiscal years, OCR's responsibilities have expanded significantly. This is due in large measure to public and stakeholder awareness of OCR's enforcement authority, increasing legal authority with respect to business associates under HIPAA, Section 1557 of the Affordable Care Act, and efficiencies that OCR has created for the public and stakeholder's to be able to access OCR's processes and services. As a result, OCR has received a significant influx of HIPAA Privacy and Security Rule

complaints and noteworthy and highly publicized breach reports (as well as a substantial number of smaller breach reports) pertaining to the HIPAA Privacy and Security Rules. In addition, OCR expects that its enhanced jurisdiction under Section 1557 and the attention being paid to developments under that authority will further add to OCR's heavy workload. OCR continues to undertake its expanded authorities without a corresponding influx of resources to match.

Case Statistics

In FY 2015, OCR provided unparalleled support to the American public: 20,560 cases were resolved, the most in OCR history. This is a result of the establishment of CCMO and the hard work of OCR regional offices. However, despite the efficiencies gained from the centralized case management functions, the increasing number of incoming complaints is likely to continue and will significantly impact OCR's ability to keep pace. Prior to FY 2012, cases had historically increased approximately around 5% each fiscal year. Over the past three fiscal years, the annual percentage increases have been 18%, 41%, and 6% for an average increase of nearly 22%. There is no reason to suspect this yearly increase will abate. Moreover, the expectation is that the recent trend of increasing caseloads due to OCR's expanded jurisdiction (Section 1557 and HITECH), in addition to increased attention to OCR's work as a result of improved outreach and resolution of multiple high impact cases, will further increase OCR's case intake numbers.

OCR's complaints rose from 12,039 in FY 2011 to 22,617 in FY 2015 and expectations are that they will continue to rise. Since implementation of the Privacy Rule in 2003, the number of privacy and security complaints filed with OCR per year has steadily grown, from 2,268 in FY 2003 to 11,811 in FY 2013 and then to 17,771 in FY 2015. The sharp rise in recent receipts in late FY 2013 is largely attributable to a complaint web portal implemented in July 2013, which allows the public to submit complaints electronically. While the portal greatly increases the efficiency of the overall intake process, it also offers a convenient, streamlined way for the public to lodge a complaint, and the public is increasingly taking advantage of it. OCR continues to look for new and innovative approaches to support the American people as staffing decreases have occured from FY 2010 to FY 2015.

Efficiencies

To keep pace with an increasing caseload due to OCR's evolving jurisdictional responsibilities related to health information privacy and security, and civil rights, in FY 2015 OCR instituted two efficiencies described below.

A headquarters realignment was completed in February 2015. To reduce management and staff at the headquarters level and to provide maximum resources to fund regional investigative staff, OCR combined and reduced the size of the ERO and Program and Business Administration Management (PBAM) entities. OCR is currently devising a reinvestment plan to utilize the projected savings.

Accomplishments

In December 2015, The University of Washington Medicine (UWM) agreed to settle charges that it potentially violated the HIPAA Security Rule by failing to implement policies and procedures to prevent, detect, contain, and correct security violations. UWM is an affiliated covered entity, which includes designated health care components and other entities under the control of the University of Washington, including University of Washington Medical Center, the primary teaching hospital of the University of Washington School of Medicine. Affiliated covered entities must have in place appropriate policies and processes to assure HIPAA compliance with respect to each of the entities that are part of the affiliated group. The settlement includes a monetary payment of \$750,000, a corrective action plan, and annual reports on the organization's compliance efforts.

In November 2015, Lahey Hospital and Medical Center (Lahey) agreed to settle potential violations of the HIPAA Privacy and Security Rules with the OCR by paying \$850,000 and adopting a corrective action plan. Lahey is a nonprofit teaching hospital affiliated with Tufts Medical School, providing primary and specialty care in Burlington, Massachusetts. Lahey notified OCR that a laptop containing the protected health information (PHI) of 599 individuals was stolen from an unlocked treatment room overnight. In addition to the \$850,000 settlement, Lahey must address its history of noncompliance with the HIPAA Rules by providing OCR with a comprehensive, enterprise-wide risk analysis and corresponding risk management plan, as well as reporting certain events and providing evidence of compliance.

In July 2015, the Arizona Health Care Cost Containment System (AHCCCS) and the Arizona Department of Economic Security (DES), which are responsible for administration of Medicaid, CHIP, and TANF entered into an agreement with OCR to resolve national origin discrimination issues resulting from the way AHCCCS and DES implemented an Arizona law requiring State employees to report persons discovered to be unlawfully present in the United States to the U.S. Immigration and Customs Enforcement (ICE). This agreement addresses circumstances where immigrants seek public benefits for themselves, on behalf of an eligible child or on behalf of other eligible persons living in a mixed status household. AHCCCS and DES have agreed to adopt and implement OCR-approved policies and procedures providing nondiscriminatory access to public benefits, utilize public benefits applications that reduce obstacles to those seeking public benefits, provide outreach on available public benefits, and conduct staff training. This agreement follows a lengthy investigation that was a cross-regional effort.

In July 2015, St. Elizabeth's Medical Center (SEMC) agreed to settle potential violations of the HIPAA Privacy, Security and Breach Notification Rules by paying \$218,400 and adopting a robust corrective action plan to correct deficiencies in its HIPAA compliance program. OCR initiated this investigation when it received a complaint alleging noncompliance with the HIPAA Rules by SEMC workforce members. Workforce members were using an internet-based document sharing application to store documents containing electronic protected health information (ePHI) of at least 498 individuals without having analyzed the risks associated with such a practice. OCR's investigation determined that SEMC failed to timely identify and respond to the known security incident, mitigate the harmful effects of the security incident, and document the security incident and its outcome.

In February 2015, OCR entered into a Voluntary Resolution Agreement with Shiawassee County Medical Care Facility in Corunna, Michigan to resolve issues raised in OCR's review of the Medical Care Facility's compliance with Title VI of the Civil Rights Act of 1964. Title VI prohibits discrimination in the administration of any Federally-funded program based on race, color, or national origin. Shiawassee

County Medical Care Facility is a 136-bed skilled nursing facility that is Medicare and Medicaid certified. OCR's Title VI review was prompted by a nursing staff member's instruction to two other nurses to not assign African-American staff to a Caucasian Resident. The agreement requires changes in policies and procedures to implement fully the prohibition against consideration of race in staff assignments. Specifically, it requires staff training and the appointment of a Title VI Coordinator charged with overseeing the facility's overall compliance with Title VI, and responsibility for the investigation and adjudication of Title VI complaints filed internally.

Funding History

Fiscal Year	Amount
FY 2012	\$26,908,000
FY 2013	\$27,030,000
FY 2014	\$26,698,000
FY 2015	\$25,091,000
FY 2016	\$25,865,000

Budget Request

The FY 2017 request for Enforcement and Regional Operations is \$28,029,000, an increase of \$2,164,000 from the FY 2016 Enacted Level. OCR will use the additional funding to hire and cover operational costs for the staff who will enforce Section 1557 of the Affordable Care Act. The additional staff will handle an increase in complex complaints in both the regional offices and at the headquarters. The experts hired for headquarters will oversee the program, advise regional staff, consult on specific complaints, develop investigator training, and formulate outreach curricula.

Section 1557 of the Affordable Care Act (ACA) is transformative because it extends protections against sex discrimination to the health care context for the first time. OCR is working to finalize a regulation which will educate consumers about their rights and covered entities about their responsibilities. The regulation will spell out the new prohibitions on sex discrimination in detail and also comprehensively compile in a single place the standards we apply to evaluate claims of discrimination based on race, national origin, disability and age. The regulation is eagerly anticipated by the civil rights community and OCR will do an extensive public education campaign once it is finalized. OCR will also undertake initiatives that benefit covered entities, such as training curricula, to aid understanding of obligations and development of model policies and practices.

OCR has experienced, and anticipates that it will continue to experience, a significant increase in civil rights complaints received based on the considerable attention that has been and will be paid to the regulation. In addition, we have received, and will continue to receive, a substantial new volume of technical assistance requests from industry and state regulators. We estimate that these new complaints and requests will result in at least a 25% increase in workload in FY 2017. Cases and issues will be immensely complex in that they involve novel issues of law and complicated facts. This is particularly true with regard to complaints brought against insurance companies. Because insurers are much more uniformly receiving federal financial assistance than they did prior to passage of the ACA, they are more consistently going to fall under the jurisdiction of the civil rights laws. Cases involving insurance present new issues. Examples include how to evaluate whether health plans' practices of setting specialty prices for drugs used to treat HIV/AIDS, discriminate based on disability; how to determine which conditions should be treated as comparators in evaluating whether a plan's exclusion

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of particular services for a medical condition is discriminatory; and whether the analysis of liability of insurers that act as third-party administrators differs from the analysis that would apply where insurers simply offer the insurance product.

Programs and Policy

(Dollars in Thousands)

Program	FY 2015 Final	FY 2016 Enacted	FY 2017 President's Budget	FY 2017 +/- FY 2016
Budget Authority	7,899	7,453	9,196	+1,743
FTE	34	34	42	+8

Program Description

Programs and Policy consists of two components, the Civil rights Division (CRD) and Health Information Privacy (HIP), with the majority of personnel in these components located at HHS headquarters in Washington, D.C.

Civil Rights Division (CRD)

CRD performs a wide variety of critical functions to support the Department's mission to promote the health and well-being of the American public. As the component responsible for leading OCR's civil rights activities, CRD provides strategic planning for national initiatives and oversees OCR's nationwide program for civil rights enforcement, policy development, and outreach. In particular, CRD provides direction and subject matter expertise to regional staff and assists in their activities to ensure legal and policy coordination in OCR's formulation of investigative plans for complaints and compliance reviews, corrective action closure letters, voluntary compliance agreements, violation letters of finding, settlement agreements and enforcement actions. CRD also investigates and enforces high impact and complex civil rights cases and leads national compliance efforts. In addition, CRD supports the OCR Director's role as the Secretary's advisor on civil rights and is responsible for civil rights reviews of the Department's rulemaking and policy guidance, including drafting regulations and guidance to implement the civil rights provisions of the Affordable Care Act (ACA) and other statutes within OCR's jurisdiction and representing OCR on all HHS and other federal agency workgroups that address the full array of civil rights issues.

With the advent of the ACA, OCR is charged with enforcing Section 1557, a nondiscrimination provision which ensures that all individuals have equal access to health programs and activities that receive HHS funding, including insurance plans, under the Act without regard to race, color, national origin (including limited proficiency in English), disability, age, or sex. Significantly, this is the first time that sex discrimination in health care is prohibited by a federal civil rights law. To help inform our regulatory development, OCR published a Request for Information (RFI) in 2013 to seek comment from consumers, health care providers, health insurers, and other stakeholders on a wide range of topics to inform OCR's rulemaking. OCR developed a Notice of Proposed Rulemaking (NPRM) to implement Section 1557; the NPRM was issued in September and OCR is currently reviewing over 18,000 public comments. OCR expects to release a final rule on Section 1557 in the Spring of 2016. This legislation significantly expands OCR's enforcement jurisdiction. OCR has already seen an increase in complaints, many of which raise issues of first impression and important policy questions, and OCR anticipates a significant increase in complaints once the NPRM is released. CRD continues to play a pivotal role in ensuring civil rights protections in regulations and guidance promulgated under the ACA, as well as other major regulations, including the CMS rule on Home and

Community Based Services and the DOL rule on the Application of the Fair Labor Standards Act to Domestic Service.

OCR's Director chairs the HHS Language Access Steering Committee, which is responsible for implementing Executive Order 13166 requiring federal agencies to ensure meaningful access to their services. The Committee, which has representatives from every HHS Operating and Staff Division, developed a Department-wide language access plan in 2013; HHS was the first federal agency to develop individually tailored plans for each of its components. OCR is overseeing implementation of the Department-wide and individual component plans. In 2015, HHS granting agencies are adding language in grants and funding opportunity announcements that help ensure grant recipients understand their civil rights obligations, particularly with respect to providing meaningful access to their programs, activities, and services by persons with limited English proficiency.

Accomplishments

In December 2015, the OCR entered into a settlement agreement with the State of Georgia, Department of Human Services' Division of Families and Children Services Program (DFCS) to address violations of Section 504 of the Rehabilitation Act of 1973 (Section 504) and Title II of the Americans with Disabilities Act (ADA) of 1990. Following a complaint filed with HHS OCR, an investigation concluded that DFCS failed to make an individualized assessment of an individual's ability to be a Foster-Adopt parent and instead improperly used disability as a criterion to make placement decisions. DFCS administers Georgia's foster care and adoption programs and is responsible for developing the placement standards for both public and private child placing agencies. The settlement requires DFCS to implement a corrective action plan that includes review and issuance of appropriate non-discriminatory policies, procedures and training, as well as periodic review of the organization's compliance efforts

In September, 2015, OCR issued a proposed rule under Section 1557, Nondiscrimination in Health Programs and Activities, and sought public comment on the rule through November 9, 2015. The proposed rule extends nondiscrimination protections to individuals enrolled in coverage through the Health Insurance Marketplaces, other health coverage plans and holds HHS's health programs accountable under the standards of the law. OCR expects to issue a final rule on Section 1557 in 2016.

In August 2015, HHS and the Department of Justice (DOJ) issued joint technical assistance to state and local child welfare agencies and courts on the requirements of Title II of the ADA and Section 504. The technical assistance released today is part of a new partnership to help child welfare agencies protect the welfare of children and ensure compliance with nondiscrimination laws. The technical assistance addresses disability discrimination complaints received from parents who have had their children taken away from them as well as individuals who have not been given equal opportunities to become foster or adoptive parents. Noting that the goals of child welfare and disability non-discrimination are complementary, the technical assistance provides an overview of Title II of the ADA and Section 504 and examples about how to apply them in the child welfare system, including child welfare investigations, assessments, guardianship, removal of children from their homes, case planning, adoption, foster care, and family court hearings, such as termination of parental rights proceedings. It also underscores that Title II and Section 504 prohibit child welfare agencies from acting based on unfounded assumptions, generalizations, or stereotypes regarding persons with disabilities.

In July 2015, OCR and The Brooklyn Hospital Center (TBHC) entered into a voluntary resolution agreement to ensure that the Center's transgender patients receive appropriate and equitable care and

treatment under Section 1557 of the Affordable Care Act. Under the agreement, TBHC will revise its policies and procedures for admissions and intake, room assignment, non-discrimination, and grievances to ensure that transgender patients are treated equitably and fairly and receive the full benefit of TBHC's services. The Center will also train staff on its new policies, which must be approved by OCR. TBHC is a 464 licensed bed, full-service community teaching hospital located in downtown Brooklyn and is affiliated with the Mount Sinai Health System.

In March 2015, OCR and the U.S. Attorney's Office for the District of Connecticut (DOJ) announced a joint voluntary resolution agreement with St. Francis Hospital and Medical Center (SFHMC) to ensure effective communication and enhance the quality of services for persons who are deaf or hard of hearing. The matter was initiated by a complaint filed with DOJ alleging violations of Title III of the ADA and a compliance review that OCR initiated to determine whether SFHMC provides auxiliary aids and services when necessary to ensure effective communication. Section 504 and the ADA prohibit discrimination on the basis of disability and require covered entities to ensure effective communication. Under the agreement, SFHMC is obligated to take several critical steps toward improving access to appropriate communication, including: revising its policies and procedures as necessary, revising its training as necessary, and performing an assessment of the need for auxiliary aids and services for patients and their caregivers. The agreement is effective for three years, during which time both OCR and the U.S. Attorney's Office will monitor SFHMC's compliance. Additionally, the complainant was awarded \$45,000 in compensatory relief.

In January 2015, OCR and the U.S. Departments of Justice (DOJ) issued a joint letter finding disability rights violations by the Massachusetts Department of Children and Families (DCF). The Departments found that DCF violated Title II of the ADA of 1990 and Section 504, by denying a mother with developmental disabilities the opportunity to benefit from supports and reunification services over a two year period following the removal of her two-day old infant. The Departments also found that DCF failed to reasonably modify its policies, practices and procedures to accommodate the mother's disability. OCR found that DCF's actions also violated Section 504.

In 2014, OCR established a partnership with the Association of American Medical Colleges to expand OCR's medical school curriculum training on Title VI of the Civil Rights Act of 1964. During the summers of 2014 and 2015, this partnership included teaching more than 1,000 pre-medical and med-students across the country.

Health Information Privacy (HIP) Division

HIP leads OCR's national privacy, security, and breach notification programs and performs a wide variety of mission-critical functions to support healthcare organizations, OCR's ten regional offices, and the American public. HIP is responsible for policy development, including rulemaking activities to modify the HIPAA Privacy, Security, Breach Notification, and Enforcement Rules pursuant to new statutory authorities or for other purposes as necessary; issuing guidance and developing compliance and training tools; providing public education; and raising awareness of individuals' privacy rights and protections for their health information. Through its efforts to promote robust privacy and security protections, HIP plays a leading role in other health reform movements, including advancing the adoption and meaningful use of electronic health records, and assuring privacy and security concerns are appropriately addressed by the delivery mechanisms under the ACA and American Recovery and Reinvestment Act (ARRA) in research and patient safety initiatives, and in emergency preparedness and response activities. In addition, since the launch of the Precision Medicine Initiative (PMI) in January

2015, HIP has been engaged in an interdepartmental and multi-stakeholder process to advance the initiative. As part of this effort, HIP participated, along with the National Institutes for Health (NIH) and the White House Office of Science and Technology Policy, on a Privacy Working Group charged with developing the privacy and security framework for PMI. The HIP Division also administers the confidentiality provisions of the Patient Safety and Quality Improvement Act of 2005, which provide confidentiality protections for patient safety work product.

Since September 2009, HIP staff have overseen a nationwide breach reporting system required by Section 13402 of the Health Information Technology for Economic and Clinical Health (HITECH) Act requiring covered entities and business associates to file reports with the Secretary of all breaches of the privacy of unsecured protected health information. HIPAA covered entities are also required to provide prompt notification to the individuals affected by the breach. Breaches affecting 500 or more individuals automatically lead to compliance reviews. HIP refers the breach reports to OCR's regional offices for validation and investigation, and is responsible for maintaining a public listing of such breaches on the HHS web site. Breach reports that affect fewer than 500 individuals are currently treated as discretionary cases and investigated as resources permit. For breach notifications, OCR has received 1,430 reports of breaches affecting 500 or more individuals and 191,052 reports of smaller breaches. A number of the recent breaches (Anthem, Premera, etc) are the largest in the nation's history. HIP staff provides significant input into the development of compliance and enforcement strategies, as well as expert advice to regional staff in their formulation of investigative plans, letters of investigative closure, resolution agreements and corrective action plans, and notices of the imposition of civil monetary penalties following complaint investigations.

As a result of the HITECH Act, covered entities, as well as their business associates, are subject to significantly increased civil money penalties for HIPAA violations that range from \$100 to \$50,000 or more per violation with a calendar year limit of \$1,500,000 for identical violations. OCR has leveraged these higher penalty amounts to strengthen and expand its compliance and enforcement program. In 2009, HIP expanded its enforcement scope to include the HIPAA Security Rule and has overseen its integration with OCR's ongoing privacy enforcement programs. HIP provides subject matter expertise to OCR's regional offices on the Privacy, Security, and Breach Notification Rules, thereby raising the quality of the corrective actions achieved through investigations. HIP also coordinates with the DOJ on criminal referrals under HIPAA.

Accomplishments

In January 2016, OCR took an important step toward ensuring that individuals can take advantage of their HIPAA right of access. OCR released a fact sheet and the first in a series of topical Frequently Asked Questions (FAQs) to further clarify individuals' core right under HIPAA to access and obtain a copy of their health information—a right that is critical to promoting consumer engagement in health care decisionmaking and research.. This set of FAQs addresses the scope of information covered by HIPAA's access right, the limited exceptions to this right, the form and format in which information is provided to individuals, the requirement to provide access to individuals in a timely manner, and the intersection of HIPAA's right of access with the requirements for patient access under the HITECH Act's Electronic Health Record (EHR) Incentive Program. OCR will continue to develop additional guidance and other tools as necessary to ensure that individuals understand and can exercise their right to access their health information.

In January 2016, HHS moved forward on the Administration's commitment to modify the HIPAA Privacy Rule to expressly permit certain covered entities to disclose to the National Instant Criminal Background

Check System (NICS) the identities of those individuals who, for mental health reasons, already are prohibited by Federal law from having a firearm. This modification better enables the reporting of the identities of prohibited individuals to the background check system and is an important step toward improving the public's safety while continuing to strongly protect individuals' privacy interests. The final rule gives States improved flexibility to ensure accurate but limited information is reported to the NICS. This rulemaking makes clear that, under the Privacy Rule, certain covered entities are permitted to disclose limited information to the NICS. The information that can be disclosed is the limited identifying information about individuals who have been involuntarily committed to a mental institution or otherwise have been determined by a lawful authority to be a danger to themselves or others or to lack the mental capacity to manage their own affairs – that is, only about those who are covered under the pre-exisiting mental health prohibitor.

In April 2015, as part of the Administration's efforts to establish and clarify requirements and protections related to employer-sponsored wellness programs, HIP issued guidance on HIPAA Privacy and Security and Workplace Wellness Programs. The guidance clarifies the circumstances in which the HIPAA Rules apply to such programs, and outlines the privacy and security protections for participants' health information that must be in place when a wellness program is offered as part of a group health plan.

In April 2015, the Department issued the *Guide to Privacy and Security of Electronic Health Information*. OCR worked closely with the Office of the National Coordinator for Health IT (ONC) to produce this guidance to assist small health care providers in implementing privacy and security protections required by the HIPAA Rules and the meaningful use program.

OCR has continued to aggressively enforce the HIPAA Privacy, Security, and Breach Notification Rules. Since July of 2008, HIP has assisted the regional offices to impose one civil money penalty and negotiate 28 settlement agreements that included detailed corrective active plans. These actions have resulted in monetary receipts that OCR has utilized towards furthering health information privacy, security, and breach enforcement efforts.

Funding History

Fiscal Year	Amount
FY 2012	\$9,217,000
FY 2013	\$7,759,000
FY 2014	\$7,683,000
FY 2015	\$7,899,000
FY 2016	\$7,453,000

Budget Request

The FY 2017 request for Programs and Policy is \$9,196,000, an increase of \$1,743,000 from the FY 2016 Enacted Level. The increase will fund OCR's initiatives for a permanent HIPAA privacy, security, and breach notification rule audit program and the Modernizing HIPAA and Supporting Innovation in Health Care initiative. OCR will add FTE and contractors to oversee and conduct the programs.

OCR plans to conduct audits of covered entities and, for the first time, business associates, using primarily contractor support (including a security expert, privacy and breach expert, and auditors), but

also internal OCR staff resources. These audits will be focused on particular requirements of HIPAA breach notification, privacy, and security rules.

The HITECH Act provided authority for OCR to design, test, and evaluate an audit function to measure compliance with privacy, security, and breach notification requirements by covered entities and their business associates. The experience and evaluation of the methods piloted in FY 2011 and FY 2012 provided the Department with an enhanced understanding of current privacy and security risks to health information. The evaluation noted strengths of the program design and suggestions for moving forward. OCR has incorporated these ideas into its current planning for a second phase of audits. A viable audit program will add value to the compliance and enforcement mission of OCR by leveraging a proactive and systemic look at industry compliance successes and struggles, rather than the incident response efforts triggered by a complaint process. A robust audit program can generate analytical tools and methods for entity self-evaluation and prevention, fostering a culture of compliance throughout the health care sector, and serve as a foundation for appropriate enforcement action. Through widespread entity interest in and response to audit program expectations, a successful audit program can have a multiplier effect on compliance penetration beyond the number of entities selected for the audit itself.

OCR currently audits only a subset of the overall population of covered entities and business associates. OCR will target an appropriate mix of size and complexity of entities to audit, select an initial pool of several hundred covered entities who will complete a pre-audit screening questionnaire that will provide OCR with characteristics about each entity. This information will enable OCR to select those entities that best fit OCR criteria.

The Modernizing HIPAA and Supporting Innovation in Health Care initiative will lead efforts to modernize the health information privacy protections paradigm, while enabling innovations in health care, research, and technology that will improve health outcomes and reduce cyber and other security risks.

As part of the the Department's efforts to implement the Cybersecurity Information Sharing Act (CISA) of 2015, OCR has committed to: issuing appropriate guidance for management of cybersecurity by regulated entities that maps existing HIPAA regulations to the National Institute of Standards and Technology (NIST) Framework; serving as an ex officio for the CISA-required industry stakeholder task force; and the funding will expand investigative staff across all OCR regions for expanded and enhanced capabilities to investigate cyber breaches.

OCR is requesting funding to lead Departmental efforts to expand and modernize the existing privacy framework to modernize HIPAA, as well as to identify and address gaps in privacy and security protections for individual health data as a result of increased cybersecurity risks and the transformation of health care services and delivery. These efforts will involve:

- Addressing cybersecurity and other risks to health information through a combination of increased enforcement of HIPAA, implementation of the audit program authorized by the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH), and implementation of the CISA of 2015.
- Evaluating current HIPAA Privacy and Security Rule provisions to identify provisions in need of modernization and implementing guidance or regulatory changes as needed to enable

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appropriate health information sharing to meet 21st century needs and reduce regulatory complexity; and

 Addressing health privacy issues not anticipated or addressed by the original HIPAA framework, building on work already underway in various areas, including Meaningful Use and interoperability and Precision Medicine. Due to the many equities involved, these efforts will necessarily entail close coordination and collaboration with other components within the Department, such as ONC, FDA, NIH, and others, as well as other stakeholders outside of the Department.

Through this initiative, OCR will assemble a dedicated team to engage with stakeholders to obtain input on concerns, priorities, and potential solutions; to develop evidence, options and recommendations to the Department, Congress and the Administration; and to implement solutions. Where recommendations for privacy and security have already been made and adopted by FY 2017, for example in the context of the Precision Medicine Initiative now underway, OCR will devote its efforts to monitoring the implementation --and evaluating the efficacy -- of those new policies or laws; to providing enhanced guidance on the interpretation of new legal standards; and to conducting outreach, public education and technical assistance to ensure that individuals, stakeholders, and the regulated community understand their new rights and responsibilities.

Because of its role enforcing anti-discrimination laws applicable to health care providers, health plans and others, OCR is uniquely situated to ensure that new technologies and the compilation of enormous datasets are not used in ways that violate the civil rights of health care consumers. OCR will include information and advice on these civil rights protections in its public education and technical assistance efforts, and will proactively enforce relevant civil rights laws where there are indications of violations. To ensure that these efforts keep up with continuing advances, staff would be dedicated to this policy development and outreach, rather than pulled ad hoc from ongoing OCR policy and enforcement work.

Since the HIPAA Privacy and Security Rules were issued over 10 years ago, they have governed the privacy and security of health information held by health care providers, health plans, and health care clearinghouses, and have afforded individuals significant rights with respect to their information in these settings. The Rules have provided an important foundation of trust for the collection and sharing of health information by these traditional health care system entities. However, the health information environment has changed considerably since the issuance of the HIPAA Rules. There have been significant advances and innovations in health information technology, including the widespread adoption of electronic medical records and the use of cloud-based and mobile health applications by the clinical care providers, public health professionals, and individuals eager to take control of health care decisions for themselves and their families. The demand for accurate, real-time health information to support delivery system reform and power advances in medical research has increased exponentially. For example, advances in health research opportunities, such as those presented by the President's Precision Medicine Initiative, have the potential to transform health care delivery and outcomes. On a broader scale, big data analytics of vast amounts of data from various sources will enable more powerful discoveries, innovations, and advancements in our quality of life.

We can realize the full potential of these innovations only if individuals and the public at large support a more robust system for the collection, use and sharing of the personal health information and other data necessary to fuel these changes. Such support will come only to the extent the public can be assured of adequate protections for the privacy and security of their personal health information as well

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as of their right to access the information and gain the benefits of the initiatives underway. As a result, it is critical that the laws and policies that provide these rights and protections do so in ways that support the data sharing necessary to power innovation and that reflect both the full spectrum of entities that will have access to personal health data and the full range of data that will be collected.

HIPAA's Privacy and Security Rules need an update, through expanded guidance and in some cases regulatory change, to reflect the information demands of the new health ecosystem. Cybersecurity risks have increased dramatically over the past year, and hacking is now responsible for breaches of the greatest number of records in the health care system. Administrative action will be needed to comprehensively address these risks and to implement the provisions of the Cybersecurity Information Sharing Act of 2015. In addition, many new types of organizations and entities may capture, use and share data about an individual's health, and that data has expanded beyond traditional medical records to encompass genomic, lifestyle, financial, environmental and other information. Much of this health data, that reflects very private aspects of the lives of individuals, exists outside of the traditional HIPAA privacy protections for individuals' health information. Further, the increased availability of genomic data and the potential to re-identify data that was de-identified present new challenges in privacy and security protection. Finally, while individuals have a right to access their medical and health care payment records under HIPAA, such rights may not extend to research information that is generated as a result of these initiatives.

Planning and Business Administration Management

(Dollars in Thousands)

Program	FY 2015 Final	FY 2016 Enacted	FY 2017 President's Budget	FY 2017 +/- FY 2016
Budget Authority	5,808	5,480	5,480	-
FTE	25	27	27	+2

Program Description

The Division of Planning and Business Administration Management (PBAM) is focused on supporting OCR's mission through a variety of service and support functions outlined below and providing direct support to the operations of OCR's other two activities (E&RO and P&P). Almost all of PBAM's staff is located at HHS headquarters in Washington, DC. The Deputy Director for PBAM is responsible for all aspects of the operations and performance of the sections and reports through the Chief of Staff to the Director.

Budget

The Budget Team is accountable for working with leadership to formulate and execute OCR's resource requirements. Specific focus areas are: budget formulation, budget execution, travel, travel card, government purchase card, personnel (civilian and Commissioned Corps) compensation, Service and Supply Fund (SSF), interagency agreements, support to OCR's divisions and regions, financial system input, data call responses, and all other resource matters that affect ongoing OCR efforts to provide quality support.

Executive Secretariat (ES)

The ES section is responsible for agency clearance requests, Congressional and other high-level correspondence, Freedom of Information Act (FOIA) actions, performance measures, and other general administrative duties. ES also provides administrative support to the Chief of Staff and Director.

Human Resources (HR)

The HR section provides guidance to leaders, conducts the recruitment of staff personnel, and coordinates personnel support actions for headquarters and the regions. The section's key responsibilities include coordination with the Office of Human Resources (OHR), management of recruitment, application of and adherence to human resources policy, personnel transaction administration, time and attendance, facility requirements, supply purchasing, and interfacing with the labor union.

Information Technology (IT)

The IT section provides guidance and support in all IT areas to ensure that OCR systems are fully operational and that all OCR personnel have access to Departmental networks. This is accomplished via the performance of a variety of tasks, including administering OCR's proprietary Performance Information Management System (PIMS), attaining and managing contracts to support PIMS, contemplating and implementing PIMS upgrades, maintaining and replacing hardware and software, fulfilling network security requirements, and providing content management for OCR's web presence on

www.hhs.gov. The IT section is also responsible for property management and the management internal controls program.

Accomplishments

In January 2016, OCR launched a newly redesigned website. OCR receives two million visitors each year, owns eight of the top ten most visited HHS webpages, and "HIPAA" is the most searched term on hhs.gov. The new site has many new upgrades and features, including categorized information and resources for individuals, professionals, and providers; powerful search functionality, prominently displayed, most requested information on division homepages, a mobile-first platform to optimize access on mobile devices. And, site navigation and content lay out on the webpages are simplified and refined. The redesign of our website was guided by web analytics, usability testing, and feedback from our partners and the public. OCR is the first division within HHS to launch a newly designed website as part of the "Reimagined HHS.gov" project.

In September 2015, the IT staff completed the development and implementation of a series of "Smart Screens" within OCR's online complaint portal. The Smart Screens prompts complainants desiring to submit online through a series of question/response screens to guide them to the correct agency for non-jurisdictional complaints and to the correct OCR portal form for jurisdictional complaints. The portal interfaces the submitted complaint with the PIMS case management intake process for review by Centralized Case Management Operations (CCMO).

In May 2015, OCR implemented a "Shared Talents Network" to allow OCR to leverage its staff knowledge, skills, and abilities across its various programs and locations. The Network enables staff to expand their skill sets by working on specific projects from their current official duty location without having to commit to the kind of reassignments or travel that can occur with formal personnel details. For example, the Network allows investigators who have expertise in particular kinds of complex cases to be paired with someone in another office who may be confronting that type of high-impact case for the first time. It also allows regional staff, where appropriate, to provide input into, and feedback on, policy projects with headquarters staff. The Network also facilitates opportunities for staff to contribute to a program area outside of their current positions. Finally, when OCR engages in a new initiative, such as an outreach strategy or an audit program, the Network can assist in the creation of a workgroup to guide those particular efforts.

In April 2015, in preparation for the Audit Compliance Program, the IT staff implemented an on-line entity verification process. The new process insures OCR has the correct contact information for Covered Entities (CE) and Business Associates (BA) for distribution of a pre-Audit questionnaire. Additionally, for ease of submission, the IT staff also developed an on-line pre-Audit questionnaire portal.

In January 2015, the IT staff completed the migration of the breach notification database to an OCR secure environment and created the PIMS Breach module. The project was a complete redesign of the previous breach notification system and web reporting site. The breach notification system includes a portal to allow a CE or BA to securely file electronic breach notifications with added security, edit checks for better data integrity, and a more user friendly interface. Upon submission of the breach notification, the CE or BA receives a verification number and can print a copy of the completed on-line form with the verification number. This number can be used by the CE or BA when contacting OCR for further

assistance. The portal interfaces the submitted breach notification with the PIMS case management module for breach notifications affecting 500 or more people. Breach notifications affecting 500 or more people are posted to the new public breach web report site which now requires an https connection.

In September 2014, OCR closed out FY 2014 having received the highest number of Freedom of Information Act requests of any HHS/OS staff division. This was accomplished by the ES staff via a backlog reduction project and via process improvement without any additional investment of resources.

Funding History

Fiscal Year	Amount
FY 2012	\$4,813,000
FY 2013	\$4,843,000
FY 2014	\$4,417,000
FY 2015	\$5,808,000
FY 2016	\$5,480,000

Budget Request

The FY 2017 request for Planning and Business Administration Management is \$5,480,000, the same as the FY 2016 Enacted Level.

Office for Civil rights

Budget Authority by Object Class (Dollars in Thousands)

Object Class Code	Description	FY 2016 Enacted	FY 2017 President's Budget	FY 2017 +/- FY 2016
11.1	Full-time permanent	16,732	18,807	+2,075
11.3	Other than full-time permanent	702	711	+9
11.5	Other personnel compensation	296	331	+35
11.7	Military personnel	159	161	+2
Subtotal	Personnel Compensation	17,889	20,010	+2,121
12.1	Civilian personnel benefits	5,690	6,361	+671
12.2	Military benefits	78	80	+2
13.0	Benefits for former personnel	31	31	-
Total	Pay Costs	23,688	26,482	+2,794
21.0	Travel and transportation of persons	349	492	+143
22.0	Transportation of things	10 10		-
23.1	Rental payments to GSA 3,312		3,092	-220
23.3	Communications, utilities, and misc. charges	204	219	+15
24.0	Printing and reproduction	60	123	+63
25.1	Advisory and assistance services	-	-	-
25.2	Other services from non-Federal sources	113	1,326	+1,213
25.3	Other goods and services from Federal sources	10,107 9,887		-220
25.4	Operation and maintenance of facilities	347 440		+93
25.5	Research and development contracts			-
25.6	Medical care	-	-	-
25.7	Operation and maintenance of equipment	387	405	+18
25.8	Subsistence and support of persons	-	-	-
Subtotal	Other Contractual Services	10,954	12,058	+1,104
26.0	Supplies and materials	191	199	+8
31.0	Equipment	30 30		-
32.0	Land and Structures		-	
41.0	Grants, subsidies, and contributions	S		-
42.0	Insurance claims and indemnities			-
44.0	Refunds	-	-	-
Total	Non-Pay Costs	15,110	16,223	+1,113
Total	Budget Authority by Object Class	38,798	42,705	+3,907

Office for Civil rights

Salaries and Expenses (Dollars in Thousands)

Object Class Code	Description	FY 2016 Enacted	FY 2017 President's Budget	FY 2017 +/- FY 2016
11.1	Full-time permanent	16,732	18,807	+2,075
11.3	Other than full-time permanent	702	711	+9
11.5	Other personnel compensation	296	331	+35
11.7	Military personnel	159	161	+2
Subtotal	Personnel Compensation	17,889	20,010	+2,121
12.1	Civilian personnel benefits	5,690	6,361	+671
12.2	Military benefits	78	80	+2
13.0	Benefits for former personnel	31	31	-
Total	Pay Costs	23,688	26,482	+2,794
21.0	Travel and transportation of persons	349	492	+143
22.0	Transportation of things	10	10	-
23.3	Communications, utilities, and misc. charges	204	219	+15
24.0	Printing and reproduction	60	123	+63
25.1	Advisory and assistance services	-	-	-
25.2	Other services from non-Federal sources	113	1,326	+1,213
25.3	Other goods and services from Federal sources	10,107	9,887	-220
25.4	Operation and maintenance of facilities	347	440	+93
25.5	Research and development contracts	-	-	-
25.6	Medical care	-	-	-
25.7	Operation and maintenance of equipment	387	405	+18
25.8	Subsistence and support of persons	-	-	-
Subtotal	Other Contractual Services	10,954	12,058	+1,104
26.0	Supplies and materials	191	199	+8
Subtotal	Non-Pay Costs	11,768	13,101	+1,333
Total	Salary and Expenses	35,456	39,583	+4,127
23.1	Rental payments to GSA	3,312	3,092	-220
Total	Salaries, Expenses, and Rent	38,768	42,675	+3,907
Total	Direct FTE	179	197	+18

Detail of Full-Time Equivalent Employment

Detail	FY 2015 Actual Civilian	FY 2015 Actual Military	FY 2015 Actual Total	FY 2016 Estimate Civilian	FY 2016 Estimate Military	FY 2016 Estimate Total	FY 2017 Estimate Civilian	FY 2017 Estimate Military	FY 2017 Estimate Total
Direct	165	2	167	177	2	179	195	2	197
Reimbursable	3	0	3	1	0	1	1	0	1
Total FTE	168	2	170	178	2	180	196	2	198

Average GS Grade

FY 2013: GS 12 FY 2014: GS 12 FY 2015: GS 12 FY 2016: GS 12 FY 2017: GS 12

Detail of Positions

Detail	FY 2015 Actual	FY 2016 Enacted	FY 2017 Budget
Executive level I	-	-	-
Executive level II	2	2	2
Executive level III	2	3	3
Executive level IV	-	-	-
Executive level V	1	1	1
Subtotal	5	6	6
Total - Exec. Level Salaries	\$848,805	\$1,029,839	\$1,042,712
-	-	-	-
GS-15	22	22	23
GS-14	23	24	27
GS-13	30	33	37
GS-12	64	69	69
GS-11	4	4	13
GS-10	-	-	-
GS-9	8	8	9
GS-8	2	2	2
GS-7	3	3	3
GS-6	2	2	2
GS-5	1	1	1
GS-4	3	3	3
GS-3	-	-	-
GS-2	-	-	-
GS-1	-	-	-
Subtotal	162	171	189
Total - GS Salary	\$15,534,195	\$16,404,161	\$18,475,288
-	-	-	-
Average ES level			
Average ES salary	\$169,761	\$171,640	\$173,785
Average GS grade	12.9	12.8	12.8 \$97,753
Average GS Salary	\$95,890	\$95,931	\$97,753

Significant Items in Appropriations Committee Reports

DIRECTIVE	OCR RESPONSE
HOUSE: In the Explanatory Statement accompanying the fiscal year 2015 Appropriations Act, the Secretary was directed to respond expeditiously to complaints regarding violations of this provision. The Committee notes that no resolution has been made to date and reiterates its directive that such complaints be responded to immediately and that this general provision be enforced. SENATE: OCR is tasked with ensuring that individuals are not subject to unlawful discrimination in healthcare programs. However, since September 2014, three Weldon Amendment cases have been filed with OCR without resolution. The OCR process is the only recourse for plaintiffs in these cases. Therefore, the Committee directs OCR to properly investigate the pending cases and urges OCR to resolve the pending cases and urges OCR to resolve the pending cases and urges OCR to resolve the pending cases expeditiously.	HHS takes its responsibilities under the Weldon Amendment seriously and supports clear provider conscience clause protections. OCR currently has open investigations related to complaints of Weldon Amendment violations. In line with OCR policy on open investigations, OCR is unable to comment further at this time because these investigations are ongoing. HHS takes its responsibilities under the Weldon Amendment seriously and supports clear provider conscience clause protections. OCR currently has open investigations related to complaints of Weldon Amendment violations. In line with OCR policy on open investigations, OCR is unable to comment further at this time because these investigations are ongoing.