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BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD**

In the matter of application Serial Nos.:

85/499,349 for the mark **CHLORADERM**
85/499,345 for the mark **CHLORABSORB**
85/499,337 for the mark **CHLORABOND**
85/499,332 for the mark **CHLORADRAPE**

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CAREFUSION 2200, INC.,

Opposer,

v.

ENTROTECH LIFE SCIENCES, INC.,

Applicant.

Combined Opposition Proceeding No. 91-206,212

United States Patent and Trademark Office
Trademark Trial and Appeal Board
P.O. Box 1451
Alexandria, Virginia 22313-1451

APPLICANT'S NOTICE OF RELIANCE

Pursuant to Rule 704.08(c) of the Trademark Trial and Appeal Board's Manual of Procedure and 37 C.F.R. § 2.122(e), Applicant Entrotech Life Sciences, Inc. ("Applicant" or "Entrotech") hereby notifies Opposer CareFusion 2200, Inc. ("Opposer" or "CareFusion") of its reliance upon the following publicly available printed materials (identified as Exhibits I1 – I14):

Exh. No.	Document	Description	URL
I1	Annual Report of the DOH Health Care Fraud and Abuse Control Program FY 2014	Report discussing the settlement, which resolved allegations that CareFusion paid kickbacks to the physician co-chair of the Safe Practices Committee at the National Quality Forum, a nonprofit organization that reviews, endorses, and recommends standardized health care performance measures and practices; and that CareFusion knowingly promoted the sale of ChloroPrep for uses that the FDA had not approved, some of which were not medically accepted indications, and made unsubstantiated representations about the appropriate uses of ChloroPrep.	https://oig.hhs.gov/publications/docs/hcfac/FY2014-hcfac.pdf
I2	CareFusion Product Poster	Poster showing use of CHLORAPREP mark	http://www.carefusion.com/pdf/Infection_Prevention/ChloroPrep-1-mL-applicator-in-service-poster.pdf
I3	ChloroPrep Safety Data Sheet	Data sheet showing use of CHLORAPREP mark	http://www.carefusion.com/pdf/Infection_Prevention/ChloroPrep_Solutions_SDS_US.pdf
I4	ChloroShield Brochure	Brochure showing use of CHLORASHIELD mark	http://www.carefusion.com/pdf/Infection_Prevention/ChloroShield-brochure.pdf
I5	ChloroPrep Label Change Fact Sheet	Fact sheet showing the ChloroPrep products (swabsticks, applicators, etc.) subject to the 2013 FDA requested label change	http://www.carefusion.com/pdf/Infection_Prevention/Labels/IP_CHP-label-change-fact-sheet_FQ_EN.pdf
I6	ChloroPrep 3mL Applicator Poster	CareFusion Product Poster – showing CHLORAPREP Products	http://www.carefusion.com/pdf/Infection_Prevention/ChloroPrep_3mL_In-Service_Poster.pdf
I7	ChloroPrep 10.5mL Applicator Poster	CareFusion Product Poster – showing CHLORAPREP Products	http://www.carefusion.com/pdf/Infection_Prevention/ChloroPrep_10I5mL_In-Service_Poster.pdf
I8	ChloroPrep 26mL Applicator Poster	CareFusion Product Poster – showing CHLORAPREP Products	http://www.carefusion.com/pdf/Infection_Prevention/ChloroPrep_26mL_In-Service_Poster.pdf

Exh. No.	Document	Description	URL
			on/ChloroPrep 26mL In-Service Poster.pdf
I9	ChloroPrep 26mL Applicator for Cesarean Section Poster	CareFusion Product Poster – showing CHLORAPREP Products	http://www.carefusion.com/pdf/Infection_Prevention/26mL_Cesarean_In-Service_Poster.pdf
I10	ChloroPrep brand Frepp 1.5 mL Applicator Poster	CareFusion Product Poster – showing CHLORAPREP Products	http://www.carefusion.com/pdf/Infection_Prevention/IP_CP_FREPP_InService.pdf
I11	ChloroPrep Sepp 0.67mL Applicator Poster	CareFusion Product Poster – showing CHLORAPREP Products	http://www.carefusion.com/pdf/Infection_Prevention/IP_CP_SEPP_InService.pdf
I12	ChloroPrep swabstick 1.75/5.25 mL Applicator Poster	CareFusion Product Poster – showing CHLORAPREP Products	http://www.carefusion.com/pdf/Infection_Prevention/IP_CP_Swabstick_InService.pdf
I13	Trichlor-O-Cide® XP-160 Packaging Insert	Packaging insert showing that Trichlor-O-Cide® XP-160 is a powdered, chlorinated, multi-purpose sanitizer.	http://chemstarworks.com/wp-content/uploads/2009/07/TrichlorOCideXP160.pdf
I14	ChlorCid® Packaging Insert	Packaging insert showing that ChlorCid® is an aqueous solution not exceeding 3.0% sodium hypochlorite with surfactants.	http://www.ahrendental.com/files/30304.5_chlorcid.pdf

Applicant will rely upon these publicly available printed materials to establish:

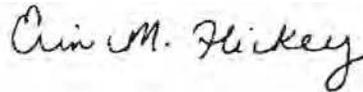
- (1) that confusion between Applicant’s CHLORADERM, CHLORABSORB, CHLORABOND, and CHLORADRAPE marks at issue in this Opposition, on the one hand, and Opposer’s CHLORAPREP and CHLORASHIELD marks at issue in this Opposition, on the other hand, is not likely; (2) the dissimilarity of the marks at issue in this Opposition; (3) the dissimilarity of the goods at issue in this Opposition; (4) the dissimilarity of the channels of trade and marketing/advertising at issue in this Opposition; (5) the purchasing conditions and the sophistication of the purchasers of the goods at issue in this Opposition; (6) the weakness of Opposer’s CHLORAPREP and CHLORASHIELD

marks; (7) the scope of Opposer's use of its CHLORAPREP and CHLORASHIELD marks; (8) the co-existence in the marketplace of Opposer's CHLORAPREP and CHLORASHIELD marks with other marks containing the letters "C-H-L-O-R" for goods relevant to this Opposition and relevant to the goods at issue in this Opposition; and (9) the reputation of Opposer in the industry.

Dated: May 21, 2015

Respectfully submitted,

FISH & RICHARDSON P.C.



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EXHIBIT I1

Annual Report of the Departments of Health and Human Services and Justice



Health Care Fraud and Abuse Control Program FY 2014

**The Department of Health and Human Services
and
The Department of Justice
Health Care Fraud and Abuse Control Program
Annual Report for Fiscal Year 2014**

March 19, 2015

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GENERAL NOTE

All years are fiscal years unless otherwise
noted in the text.

EXECUTIVE SUMMARY

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) established a national Health Care Fraud and Abuse Control Program (HCFAC or the Program) under the joint direction of the Attorney General and the Secretary of the Department of Health and Human Services (HHS)¹, acting through the Inspector General, designed to coordinate Federal, state and local law enforcement activities with respect to health care fraud and abuse. In its eighteenth year of operation, the Program's continued success confirms the soundness of a collaborative approach to identify and prosecute the most egregious instances of health care fraud, to prevent future fraud and abuse, and to protect program beneficiaries.

Monetary Results

During Fiscal Year (FY) 2014, the Federal government won or negotiated over \$2.3 billion in health care fraud judgments and settlements², and it attained additional administrative impositions in health care fraud cases and proceedings. As a result of these efforts, as well as those of preceding years, in FY 2014, approximately \$3.3 billion returned to the Federal government or paid to private persons. Of this \$3.3 billion, the Medicare Trust Funds³ received transfers of approximately \$1.9 billion during this period, and over \$523 million in Federal Medicaid money was similarly transferred separately to the Treasury as a result of these efforts. The HCFAC account has returned over \$27.8 billion to the Medicare Trust Funds since the inception of the Program in 1997.

Enforcement Actions

In FY 2014, the Department of Justice (DOJ) opened 924 new criminal health care fraud investigations. Federal prosecutors filed criminal charges in 496 cases involving 805 defendants. A total of 734 defendants were convicted of health care fraud-related crimes during the year. Also in FY 2014, DOJ opened 782 new civil health care fraud investigations and had 957 civil health care fraud matters pending at the end of the fiscal year. In FY 2014, the FBI investigative efforts resulted in over 605 operational disruptions of criminal fraud organizations and the dismantlement of the criminal hierarchy of more than 142 health care fraud criminal enterprises.

In FY 2014, HHS' Office of Inspector General (HHS-OIG) investigations resulted in 867 criminal actions against individuals or entities that engaged in crimes related to Medicare and Medicaid, and 529 civil actions, which include false claims and unjust-enrichment lawsuits filed in Federal district court, civil monetary penalties (CMP) settlements, and administrative recoveries related to provider self-disclosure matters. HHS-OIG also excluded 4,017 individuals

¹ Hereafter, referred to as the Secretary.

² The amount reported as won or negotiated only reflects the Federal recoveries and therefore does not reflect state Medicaid monies recovered as part of any global Federal-State settlements.

³ Also known as the Medicare Hospital Insurance (Part A) Trust Fund and the Supplemental Medical Insurance (Part B) Trust Fund.

and entities from participation in Medicare, Medicaid, and other federal health care programs. Among these were exclusions based on criminal convictions for crimes related to Medicare and Medicaid (1,310) or to other health care programs (432), for patient abuse or neglect (189), and as a result of licensure revocations (1,744). HHS-OIG also issued numerous audits and evaluations with recommendations that, when implemented, would correct program vulnerabilities and save program funds.

Sequestration Impact

Due to sequestration of mandatory funding in 2014, there were fewer resources for DOJ, FBI, HHS, and HHS-OIG to fight fraud and abuses against Medicare, Medicaid, and other health care programs. A total of \$31.5 million was sequestered from the HCFAC program in FY 2014, for a combined total of \$62.1 million in the past two years.

INTRODUCTION

The Annual Report of the Attorney General and the Secretary detailing expenditures and revenues under the Health Care Fraud and Abuse Control Program for Fiscal Year 2014 is provided as required by Section 1817(k)(5) of the Social Security Act.

Statutory Background

The Social Security Act Section 1128C(a), as established by the Health Insurance Portability and Accountability Act of 1996 (P.L. 104-191, HIPAA or the Act), created the Health Care Fraud and Abuse Control Program, a far-reaching program to combat fraud and abuse in health care, including both public and private health plans.

As was the case before HIPAA, amounts paid to Medicare in restitution or for compensatory damages must be deposited in the Medicare Trust Funds. The Act requires that an amount equaling recoveries from health care investigations – including criminal fines, forfeitures, civil settlements and judgments, and administrative penalties – also be deposited in the Trust Funds.

The Act appropriates monies from the Medicare Hospital Insurance Trust Fund to an expenditure account, called the Health Care Fraud and Abuse Control Account (the Account), in amounts that the Secretary and Attorney General jointly certify as necessary to finance anti-fraud activities. The maximum amounts available for certification are specified in the Act. Certain of these sums are to be used only for activities of the HHS-OIG, with respect to the Medicare and Medicaid programs. In FY 2006, the Tax Relief and Health Care Act (TRHCA) (P.L. 109-432, §303) amended the Act so that funds allotted from the Account are “available until expended.” TRHCA also allowed for yearly increases to the Account based on the change in the consumer price index for all urban consumers (all items, United States city average) (CPI-U) over the previous fiscal year for fiscal years for 2007 through 2010.⁴ In FY 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively referred to as the Affordable Care Act (P.L. 111-148, ACA) extended permanently the yearly increases to the Account based upon the change in the consumer price index for all urban consumers, or CPI-U.

In FY 2014, the Secretary and the Attorney General certified \$278.1 million in mandatory funding to the Account after accounting for sequester reductions of \$21.6 million to the total appropriation. Additionally, Congress appropriated \$293.6 million in discretionary funding. A detailed breakdown of the allocation of these funds is set forth later in this report. HCFAC appropriations generally supplement the direct appropriations of HHS and DOJ that are devoted to health care fraud enforcement and funded approximately three-fourths of HHS-OIG’s

⁴ The CPI-U adjustment in TRHCA did not apply to the Medicare Integrity Program (MIP). Section 6402 of the ACA indexed Medicare Integrity Program funding to inflation starting in FY 2010.

appropriated budget in FY 2014. (Separately, the FBI received \$127.3 million from HIPAA—after accounting for \$9.9 million in mandatory sequester reductions—which is discussed in the Appendix.)

Under the joint direction of the Attorney General and the Secretary, the Program’s goals are:

- (1) to coordinate Federal, state and local law enforcement efforts relating to health care fraud and abuse with respect to health plans;
- (2) to conduct investigations, audits, inspections, and evaluations relating to the delivery of and payment for health care in the United States;
- (3) to facilitate enforcement of all applicable remedies for such fraud; and
- (4) to provide education and guidance regarding complying with current health care law.

The Act requires the Attorney General and the Secretary to submit a joint annual report to the Congress that identifies both:

- (1) the amounts appropriated to the Trust Funds for the previous fiscal year under various categories and the source of such amounts; and
- (2) the amounts appropriated from the Trust Funds for such year for use by the Attorney General and the Secretary and the justification for the expenditure of such amounts.

This annual report fulfills the above statutory requirements.

Additionally, this report fulfills the requirement in the annual discretionary HCFAC appropriation (Public Law 113-76 “Consolidated Appropriations Act, 2014”) that this report “include measures of the operational efficiency and impact on fraud, waste, and abuse in the Medicare, Medicaid, and CHIP programs for the funds provided by this appropriation.”

MONETARY RESULTS

As required by the Act, HHS and DOJ must detail in this Annual Report the amounts deposited to the Medicare Trust Funds and the source of such deposits. In FY 2014, approximately \$3.3 billion was deposited with the Department of the Treasury and CMS, transferred to other Federal agencies administering health care programs, or paid to private persons during the fiscal year. The following chart provides a breakdown of the transfers/deposits:

Total Transfers/Deposits by Recipient FY 2014	
Department of the Treasury	Amount
Deposits to the Medicare Trust Funds, as required by HIPAA	
Gifts and Bequests	\$7,117
Amount Equal to Criminal Fines	344,378,820
Civil Monetary Penalties	23,559,109
Asset Forfeiture	24,675,735
Penalties and Multiple Damages	807,446,537
Subtotal	1,200,067,319
Centers for Medicare & Medicaid Services	
HHS-OIG Audit Disallowances – Recovered - Medicare	102,159,881
Restitution/Compensatory Damages	608,811,471
Subtotal*	710,971,352
	\$1,911,038,671
Total of Amounts Transferred to the Medicare Trust Funds	
Restitution/Compensatory Damages to Federal Agencies	
TRICARE	\$23,393,642
Department of Veterans Affairs	52,352,227
HHS-OIG Cost of Audits, Investigations and Compliance Monitoring	11,194,863
Office of Personnel Management	48,823,213
Other Agencies	13,902,582
Centers for Medicare and Medicaid Services	
Federal Share of Medicaid	522,788,332
HHS-OIG Audit Disallowances – Recovered - Medicaid	358,696,627
Subtotal	1,031,151,487
Relators' Payments**	369,178,807
GRAND TOTAL ***	\$3,311,368,964

*Restitution, compensatory damages, and recovered audit disallowances include returns to both the Medicare Hospital Insurance (Part A) Trust Fund and the Supplemental Medical Insurance (Part B) Trust Fund.

**These are funds awarded to private persons who file suits on behalf of the Federal government under the qui tam (whistleblower) provisions of the False Claims Act, 31 U.S.C. § 3730(b).

***State funds are also collected on behalf of state Medicaid programs; only the Federal share of Medicaid funds transferred to CMS are represented here.

The above transfers include certain collections, or amounts equal to certain collections, required by HIPAA to be deposited directly into the Medicare Trust Funds. These amounts include:

- (1) Gifts and bequests made unconditionally to the Trust Funds, for the benefit of the Account or any activity financed through the Account;
- (2) Criminal fines recovered in cases involving a federal health care offense, including collections under section 24(a) of Title 18, United States Code (relating to health care fraud);
- (3) Civil monetary penalties in cases involving a federal health care offense;
- (4) Amounts resulting from the forfeiture of property by reason of a federal health care offense, including collections under section 982(a)(7) of Title 18, United States Code; and
- (5) Penalties and damages obtained and otherwise creditable to miscellaneous receipts of the general fund of the Treasury obtained under sections 3729 through 3733 of Title 31, United States Code (known as the False Claims Act, or FCA), in cases involving claims related to the provision of health care items and services (other than funds awarded to a relator, for restitution or otherwise authorized by law).

Expenditures

In the eighteenth year of operation, the Secretary and the Attorney General certified \$278.1 million in mandatory funding as necessary for the Program, after accounting for mandatory sequester reductions of \$21.6 million as required by law. Additionally, Congress appropriated \$293.6 million in discretionary funding. The chart below gives the allocation by recipient:

FY 2014 ALLOCATION OF HCFAC APPROPRIATION				
Organization	Mandatory Allocation⁵	Discretionary Allocation	Funds Sequester	Total Allocation
Department of Health and Human Services				
Office of Inspector General ⁶	\$199,330,986	\$28,122,000	(\$14,351,831)	\$213,101,155
Office of the General Counsel	13,000,000	0		13,000,000
Administration for Community Living	6,590,974	0		6,590,974
Food and Drug Administration	2,288,504	0		2,288,504
Centers for Medicare & Medicaid Services	13,500,000	237,344,000		250,844,000
Unallocated Funding	2,744,960	0	(2,744,960)	0
Subtotal	237,455,424	265,466,000	(17,096,791)	485,824,633
Department of Justice				
United States Attorneys	31,400,000	9,332,010	0	40,732,010
Civil Division	17,934,067	8,213,107	0	26,147,174
Criminal Division	2,418,072	6,152,883	0	8,570,955
Civil Rights Division	2,376,000	4,424,000	0	6,800,000
Nursing Home and Elder Justice Initiative	1,000,000	0	0	1,000,000
Justice Management Division	200,000	0	0	200,000
Department of Justice - Other	6,908,482	0	(4,481,037)	2,427,445
Subtotal	62,236,621	28,122,000	(4,481,037)	85,877,584
TOTAL⁷	\$299,692,045	\$293,588,000	(\$21,577,828)	\$571,702,217

⁵As of FY 2007, mandatory funds are available until expended. Discretionary funds are available for two years.

⁶In addition, HHS-OIG obligated \$11.2 million in funds received as "reimbursement for the costs of conducting investigations and audits and for monitoring compliance plans" as authorized by section 1128C(b) of the Social Security Act, 42 U.S.C. § 1320a-7c(b).

⁷Amounts only represent those that are provided by statute, and do not include other mandatory sources or discretionary appropriated sources provided through Departments' annual appropriations.

PROGRAM ACCOMPLISHMENTS

Overall Recoveries

During this fiscal year, the Federal government won or negotiated approximately \$3.3 billion in judgments and settlements, and it attained additional administrative impositions in health care fraud cases and proceedings. The Medicare Trust Funds received transfers of approximately \$1.9 billion during this period as a result of these efforts, as well as those of preceding years; and another \$523 million in Federal Medicaid money was transferred to the Treasury separately as a result of these efforts.⁸

In addition to these enforcement actions, numerous audits, evaluations and other coordinated efforts yielded recoveries of overpaid funds, and prompted changes in federal health care programs that reduce vulnerability to fraud.

The return on investment (ROI) for the HCFAC program over the last three years (2012-2014) is \$7.70 returned for every \$1.00 expended. This is \$2 higher than the average ROI for the life of the HCFAC program since 1997 and the third highest ROI overall. Since the annual ROI can vary from year to year depending on the number and type of cases that are settled or adjudicated during that year, DOJ and HHS use a three-year rolling average ROI for results contained in the report. Additional information on how the ROI is calculated can be found in the Appendix.

Departmental Collaboration

Health Care Fraud Prevention & Enforcement Action Team (HEAT)

The Attorney General and the Secretary maintain regular consultation at both senior and staff levels to accomplish the goals of the HCFAC Program. On May 20, 2009, Attorney General Holder and Secretary Sebelius announced the Health Care Fraud Prevention & Enforcement Action Team (HEAT), a new effort with increased tools and resources, and a sustained focus by senior level leadership to enhance collaboration between the Departments of Health and Human Services and Justice. With the creation of the new HEAT effort, DOJ and HHS pledged a Cabinet-level commitment to prevent and prosecute health care fraud. HEAT, which is jointly led by the Deputy Attorney General and HHS Deputy Secretary, is comprised of top level law enforcement agents, prosecutors, attorneys, auditors, evaluators, and other staff from DOJ and HHS and their operating divisions, and is dedicated to joint efforts across government to both prevent fraud and enforce current anti-fraud laws around the country. The Medicare Fraud Strike Force teams are a key component of HEAT.

⁸ Note that some of the judgments, settlements, and administrative actions that occurred in FY 2014 will result in transfers in future years, just as some of the transfers in FY 2014 are attributable to actions from prior years.

The mission of HEAT is:

- **To marshal significant resources across government to prevent waste, fraud and abuse in the Medicare and Medicaid programs** and crack down on the fraud perpetrators who are abusing the system and costing us all billions of dollars.
- **To reduce skyrocketing health care costs and improve the quality of care** by ridding the system of perpetrators who are preying on Medicare and Medicaid beneficiaries.
- **To highlight best practices by providers and public sector employees** who are dedicated to ending waste, fraud, and abuse in Medicare.
- **To build upon existing partnerships between DOJ and HHS, such as our Medicare Fraud Strike Force Teams**, to reduce fraud and recover taxpayer dollars.

Since its creation in May 2009, HEAT has focused on key areas for coordination and improvement. HEAT members are working to identify new enforcement initiatives and areas for increased oversight and prevention to increase efficiency in areas such as pharmaceutical and device investigations. DOJ and HHS have expanded data sharing and improved information sharing procedures in order to get critical data and information into the hands of law enforcement to track patterns of fraud and abuse and increase efficiency in investigating and prosecuting complex health care fraud cases. The departments established a cross-government health care fraud data intelligence sharing workgroup to share fraud trends, new initiatives, ideas, and success stories to improve awareness across the government of issues relating to health care fraud.

Both departments also have developed training programs to prevent honest mistakes and help stop potential fraud before it happens. This includes CMS compliance training for providers, HHS-OIG's HEAT Provider Compliance Training initiative, on-going meetings at U.S. Attorneys' Offices (USAOs) with the public and private sector, and increased efforts by HHS to educate specific groups – including elderly and immigrant communities – to help protect them. In addition, DOJ conducts, with the support of HHS, a Medicare Fraud Strike Force training program designed to teach the Strike Force concept and case model to prosecutors, law enforcement agents, and administrative support teams.

Healthcare Fraud Prevention Partnership (HFPP)

The Healthcare Fraud Prevention Partnership (HFPP) is the groundbreaking public/private partnership between the government and private sector insurance payers. The purpose of the partnership is to exchange data and information between the partners to help improve capabilities to fight fraud, waste and abuse in the health care industry. Current partners include the Federal Government (HHS-OIG, DOJ, FBI, and CMS), states, private plans and associations. Since its inception, the number of participants has increased to 37 public, private and state partner organizations. The Partnership has completed several studies associated with fraud, waste or abuse that have yielded successful results for participating partners. Studies have examined "False Store Fronts" or "phantom providers," entity revocation/termination lists and top billing pharmacies. Additional studies are underway and the Partnership has established a Trusted Third Party (TTP) which conducts HFPP data exchanges, research, data consolidation and aggregation,

reporting, and analysis. The TTP will not share the source of the data (i.e., which partner submitted what data) during an exchange in order to keep the identity of the data source confidential. HFPP is continuing to expand with new partners.

The Partnership is a demonstrated example of effective departmental collaboration between HHS and DOJ, working together to create a strong partnership with the states and private payers to detect fraud, waste, and abuse. In FY 2014, the Partnership hosted its fourth bi-annual Executive Board meeting. The meeting focused on developing a strategy to ensure the productivity of the Partnership and highlighted achievements and progress since the last meeting including data exchanges, information sharing, and partnership growth.

Medicare Fraud Strike Force

The first Medicare Fraud Strike Force (Strike Force) was launched in March 2007 as part of the South Florida Initiative, a joint investigative and prosecutorial effort against Medicare fraud and abuse in South Florida. The Strike Force is comprised of interagency teams made up of investigators and prosecutors that focus on the worse offenders engaged in fraud in the highest intensity regions. The Strike Force uses advanced data analysis techniques to identify aberrant billing levels in health care fraud “hot spots” – cities with high levels of billing fraud – and target suspicious billing patterns as well as emerging schemes and schemes that migrate from one community to another. Based on the success of these efforts and increased appropriated funding for the HCFAC program from Congress and the Administration, DOJ and HHS expanded Strike Force operations to a total of nine areas – Miami, FL; Los Angeles, CA; Detroit, MI; Houston, TX; Brooklyn, NY; Southern Louisiana; Tampa, FL; Chicago, IL; and Dallas, TX.

Each Medicare Fraud Strike Force team brings the investigative and analytical resources of the FBI and HHS-OIG and the prosecutorial resources of the Criminal Division’s Fraud Section and the USAOs to analyze data obtained from CMS and bring cases in federal district court. Strike Force accomplishments from cases prosecuted in all nine areas during FY 2014 include⁹:

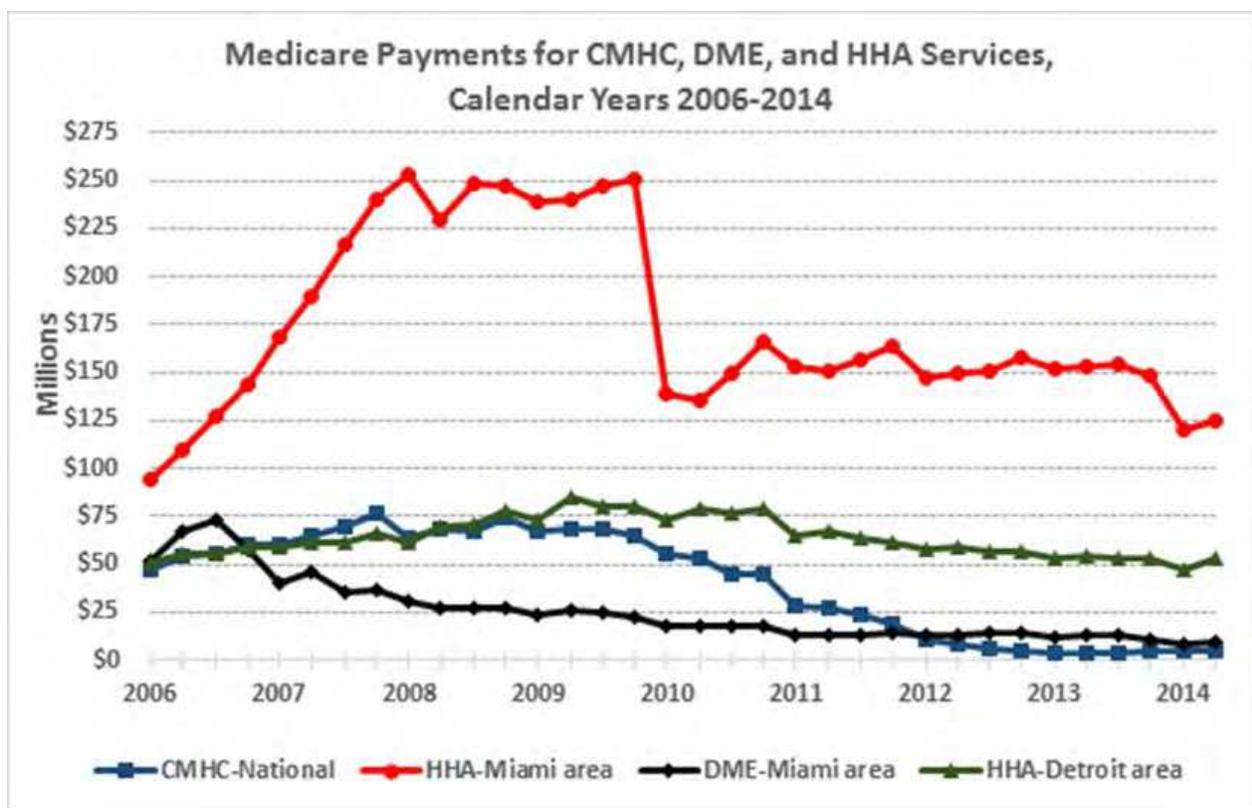
- 165 indictments, informations and complaints involving charges filed against 353 defendants who allegedly collectively billed the Medicare program approximately \$830 million;
- 304 guilty pleas negotiated and 38 jury trials litigated, with guilty verdicts against 41 defendants; and
- Imprisonment for 248 defendants sentenced during the fiscal year, averaging more than 50 months of incarceration.

In the seven and a half years since its inception, Strike Force prosecutors filed more than 963 cases charging more than 2,097 defendants who collectively billed the Medicare program

⁹ The accomplishments figures presented in the bullets include all reported Strike force cases handled by DOJ Criminal Division attorneys and AUSAs in the respective USAOs during FY 2014.

more than \$6.5 billion; 1,443 defendants pleaded guilty and 191 others were convicted in jury trials; and 1,197 defendants were sentenced to imprisonment for an average term of approximately 47 months.¹⁰

Medicare payment trends demonstrate the positive impact of Strike Force enforcement and prevention efforts. For example, Medicare payments for home health care increased from 2006 until 2010. In 2009, CMS changed Medicare’s Home Health Agency (HHA) outlier coverage policy following federal enforcement actions initiated by the HEAT Strike Force case *U.S. v. Zambrana* in Miami and HHS-OIG reports regarding home health outlier payments. As reflected on the chart below, since 2010, Medicare payments for home health care nationally decreased by more than \$300 million per quarter (or more than \$1 billion annually). In Miami, payments for HHAs decreased by \$100 million per quarter since the peak in 2009; in Dallas and McAllen, Texas, payments for HHAs are down by \$30 million per quarter; while in Detroit, payments for HHAs decreased by \$25 million per quarter since peak in 2009. This may suggest that the home health fraud convictions not only eliminated some of the “bad actors” but also deterred other fraudsters from exploiting the outlier coverage policy. We have seen similar patterns of decreased Medicare payments for DME and community mental health services (CMHC) following concentrated law enforcement initiatives and administrative fraud prevention efforts.



¹⁰ These statistics are for the period of May 7, 2007 through September 30, 2014.

Examples of successful cases initiated or concluded in districts where Strike Force prosecution teams were operational during FY 2014, as well as other successful cases are provided below. Summaries of additional successful prosecutions and settlements follow, organized by fraud type.

Miami (Southern District of Florida)

- In November 2013, the owners of Trust Care Health Services, Inc. and several other home health care companies were sentenced for their roles in a health care fraud scheme with losses of approximately \$50 million. According to court documents, the owners of these facilities paid kickbacks to patient recruiters in return for referring patients for home health and therapy services that were not medically necessary and were not provided. Payments were also made to co-conspirators in doctors' offices and clinics in exchange for fraudulent home health and therapy prescriptions and medical certifications, which were used to fraudulently bill the Medicare program for home health care services between 2007 and 2013. The defendants were each sentenced to prison terms ranging from 60 to 120 months, and were collectively ordered to pay more than \$25 million in restitution.
- In December 2013, the owner of Anna Nursing Services Corp. was sentenced to 235 months in prison for her role in a health care fraud scheme with losses of approximately \$7 million. According to evidence presented at trial, the owner operated this facility from 2010 to 2013 for the purpose of billing the Medicare Program for, among other things, expensive physical therapy and home health care services that were neither medically necessary nor provided. After trial, she was found guilty of conspiracy to commit health care fraud, conspiracy to pay health care kickbacks, conspiracy to commit money laundering, in addition to other related charges. Other participants in the scheme were also sentenced in December 2013 to prison terms ranging from 46 months to 50 months in prison.
- In March 2014, the owner of a health care clinic was sentenced to 108 months in prison for her role in multiple health care fraud schemes with estimated losses of more than \$20 million. The clinic, Merfi Corp., employed physicians, physician assistants, and other medical professionals who dispensed fraudulent prescriptions for, among other things, home health care services. Through this company, the owner and her co-conspirators provided home health prescriptions and medical certifications to the owners and operators of home health care agencies and to patient recruiters in return for kickbacks and bribes. This documentation was used to fraudulently bill the Medicare program for physical therapy and other home health care services.
- In May 2014, the director of the outpatient facility at Hollywood Pavilion, LLC, which purportedly provided mental health services to Medicare beneficiaries, was sentenced to six years in prison and was ordered to pay \$39 million in joint and several restitution. According to court documents, the director and her co-conspirators arranged for illegal bribes and kickbacks to be paid to "patient brokers" in return for referring Medicare beneficiaries to Hollywood Pavilion. The director and her co-conspirators then caused the

submission of fraudulent claims through Hollywood Pavilion and billed the Medicare program millions of dollars for services that were medically unnecessary and for services provided to patients who were not eligible for treatment. In an attempt to conceal the fraud, the director and her co-conspirators caused false, inaccurate, and misleading information to be included in patient files and related documents for Medicare beneficiaries who were purportedly receiving mental health treatment at Hollywood Pavilion. The director was convicted on charges of conspiracy to commit health care and wire fraud, wire fraud, and conspiracy to pay and receive kickbacks in connection with a federal health care benefit program.

- In May 2014, two defendants were indicted for their roles in a complex Medicare fraud and money laundering scheme in the Southern District of Florida. The alleged schemes center on a corrupt relationship with a co-conspirator, the former owner and operator of Pharmovisa, Inc. and PharmovisaMD, Inc., a defunct pharmacy and DME provider in Miami, Florida. According to the indictment, this co-conspirator paid kickbacks to the defendants through shell companies under their control in order to gain access to patient information. The information was later used to submit more than \$23 million in fraudulent claims to the Medicare Part D program. This co-conspirator previously pleaded guilty to conspiracy to commit health care fraud and conspiracy to pay and receive health care kickbacks and was sentenced to 168 months in prison.
- In May 2013 and July 2014, an administrator and an owner were convicted for their roles in a \$74 million home health fraud scheme. Two home health agencies, LTC Home Care Professionals, Inc. (LTC) and Professional Home Care Solutions, Inc., purported to provide home health care and physical therapy services to Medicare beneficiaries. These two defendants and their co-conspirators paid kickbacks and bribes to patient recruiters, who provided patients to LTC and Professional Home Care, as well as prescriptions, plans of care (POCs) and certifications for medically unnecessary therapy and home health services for Medicare beneficiaries. The defendants and their co-conspirators used these prescriptions, POCs and medical certifications to fraudulently bill the Medicare program for home health care services. From approximately January 2006 to June 2012, LTC and Professional Home Care submitted approximately \$74 million in claims for home health services that were not medically necessary and/or not provided, and Medicare paid approximately \$45 million on those claims.

Los Angeles (Central District of California)

- In October 2013, three of four defendants pled guilty to conspiracy to commit health care fraud. These charges stemmed from a \$49 million fraud in which the defendants were providing medically unnecessary, non-emergency ambulance transportation services to Medicare beneficiaries, primarily to dialysis patients. These three defendants were later sentenced to prison terms ranging from 30 to 108 months. The fourth defendant, a manager at the ambulance company, went to trial in September 2014; he pled guilty midway through trial.

- In October 2013, five defendants were sentenced for their role in an extensive \$11 million DME fraud conspiracy. Each of the defendants received sentences ranging from 12 to 87 months in prison.
- In March 2014, an owner of a DME company was convicted after a jury trial for his role in a \$1.5 million Medicare fraud conspiracy. He was found guilty of one count of conspiracy to commit health care fraud, six counts of health care fraud, and six counts of aggravated identity theft. The evidence at trial established that the defendant and his co-conspirator operated a company called Orthomed Appliance, Inc., and stole the personal identifying information of Medicare beneficiaries and doctors. The defendant used that stolen information to submit more than \$1.5 million in fraudulent claims to Medicare. In July 2014, he was sentenced to 121 months in prison.
- In July 2014, the owner and operator of Lutemi Medical Supply, a DME supply company, was convicted at trial for conspiracy, health care fraud, and money laundering in connection with an \$8.3 million, ten-year Medicare fraud scheme. The evidence at trial showed that the defendant submitted fraudulent prescriptions for DME, primarily power wheelchairs and related accessories, by using street-level patient recruiters or "marketers" to find Medicare eligible beneficiaries. The marketers then took the beneficiaries to doctors who prescribed medically unnecessary prescriptions, and the defendant and her co-conspirators paid illegal kickbacks to the marketers and the doctors. In total, the defendant submitted claims to Medicare for more than 1,000 power wheelchairs.
- In August 2014, the owner of a medical clinic management company pled guilty to conspiracy for his role in a \$3 million health care fraud scheme that involved two medical clinics. The defendant and his co-conspirators hired physician's assistants to sign prescriptions for medically unnecessary power wheelchairs, which the defendant and his co-conspirators then sold to multiple DME supply companies.

Detroit (Eastern District of Michigan)

- The Detroit Strike Force obtained significant post-trial sentences against members of a \$15 million home health care fraud conspiracy in 2014. In March 2014, the defendant, the part owner of a fraudulent home health care company who hid his ownership and laundered the proceeds of the fraud through shell corporations, received a sentence of 120 months in prison. In June 2014, another defendant, a patient recruiter with a lengthy criminal history who promised patients cash and access to narcotic prescriptions in exchange for agreeing to sign up for fraudulent home health care services, received a sentence of 86 months in prison. This case was indicted in January 2010 and resulted in a total of 20 convictions through guilty pleas and at trial.
- In April 2014, the owner and operator of TGW Medical, Inc. and Caldwell Thompson Manor, Inc. (CTM), was sentenced to 3 years and 4 months of incarceration and was ordered to pay \$5 million in joint and several restitution. The two businesses purportedly provided psychotherapy services to Medicare beneficiaries. The owner and operator of

P&C Adult Day Center, LLC, which also purportedly provided psychotherapy services, was sentenced to 3 years and 4 months of incarceration and was ordered to pay \$599,438 in joint and several restitution. According to the indictment, the owner of TGW and CTM and her co-conspirators signed patient charts and progress notes for individual and group psychotherapy sessions purportedly performed at TGW, Caldwell Thompson, and P&C that were not medically necessary and were not performed. She used her own provider number as well as the provider number of another social worker at TGW to cause the three clinics to bill Medicare approximately \$20 million for psychotherapy visits. The owner of CTM and TGW pleaded guilty to conspiracy to commit health care fraud and, in addition to her sentencing, was excluded from participating in any federal health care programs for 20 years. The owner of P&C previously pleaded guilty to conspiracy to commit health care fraud and health care fraud.

- Twenty individuals were charged between 2011 and 2014 for their roles in a \$13.8 million scheme to defraud Medicare by submitting fraudulent claims for home health care services. Fourteen of the defendants pled guilty, and three others were found guilty after trial in April and May 2014. Three remain fugitives. According to trial evidence, in exchange for kickbacks, Medicare beneficiaries pre-signed forms and visit sheets that were later falsified to indicate they received home health services they had never received. The scheme employed individuals who held themselves out to be “doctors,” but who were not, in fact, licensed in the state of Michigan to perform any medical services. The unlicensed “doctors” met and purported to examine non-homebound Medicare beneficiaries for home health care services, signed false paperwork so they could be billed through four home health agencies and provided the patients with narcotic prescriptions. The defendants were sentenced to terms of imprisonment ranging from 18 to 72 months.
- In July 2014, the last defendants in a \$67 million pharmacy health care fraud, drug diversion and kickback conspiracy were convicted at trial. Thirty-nine defendants were charged in the investigation; all were convicted, except for one who is a fugitive. The defendants, including owners, pharmacists, recruiters and doctors, were operating or helping to operate a chain of fraudulent pharmacies that illegally billed Medicare and Medicaid for expensive drugs that were never dispensed and dispensed narcotic drugs to patient recruiters who sold them on the street for profit. More than 250,000 dosage units of oxycodone and four million dosage units of hydrocodone were diverted to the scheme between 2006 and 2011.
- In September 2014, an oncologist pled guilty to 16 felony counts, including health care fraud, money laundering and kickbacks, in connection with a health care fraud scheme involving fraudulent claims for medically unnecessary cancer treatments. The defendant billed Medicare over \$225 million during the scheme, as well as tens of millions more to private insurance companies. In his guilty plea, the defendant admitted to prescribing and administering aggressive chemotherapy, cancer treatments, intravenous iron and other infusion therapies to patients who did not need them in order to increase his billings to the Medicare program and other insurance companies.

Houston (Southern District of Texas)

- In October 2013, the owner of an ambulance company was convicted by a federal jury of conspiracy to commit health care fraud and a substantive charge of health care fraud. According to court documents and trial evidence, the defendant submitted claims totaling approximately \$2.4 million to Medicare for ambulance services that were medically unnecessary, and in some cases, never provided. On June 13, 2014, the defendant was sentenced to 97 months in prison.
- In March 2014, a federal jury convicted seven individuals associated with a mental health clinic, including the owner-physicians, administrator, physician's assistant, clinical director, and patient recruiters. According to court documents and trial evidence, the defendants submitted claims to Medicare totaling approximately \$97 million for psychiatric partial hospitalization program services that were medically unnecessary, and in some cases, never provided. The sentencings are scheduled for January 2015.
- In April 2014, the owner of a home health care company and the owner of a comprehensive health care clinic both pleaded guilty to one count of conspiracy to commit health care fraud stemming from an \$8.1 million Medicare home health care fraud scheme. The owner of the home health company paid kickbacks to the health care clinic owner in addition to using her home health care company's Medicare provider number to submit claims to Medicare for home health services that were medically unnecessary, and in some cases, never provided. Sentencing is scheduled for September 2015.
- In April 2014, the director of nursing for a home health agency pleaded guilty to an over-\$4.5 million scheme to defraud Medicare. Along with the owner of the agency, she also pleaded guilty to conspiring to structure over \$1.8 million in bank withdrawals. The director of nursing pleaded to billing Medicare for home health services that were not provided and not medically necessary, as well as to conspiring with the owner to structure cash withdrawals. Together, these two defendants used the withdrawals to pay illegal health care kickbacks to recruiters who referred patients to them and to doctors for authorizing home health care.
- In June 2014, the owner of a home health company was sentenced to 151 months in prison and ordered to pay \$3 million in restitution. Her sentence was the result of an October 2013 conviction in connection with a \$3 million Medicare fraud scheme. According to court documents and trial evidence, the defendant used her company's Medicare provider number to submit claims to Medicare for home health services that were medically unnecessary, and in some cases, never provided.

Brooklyn (Eastern District of New York)

- In November 2013, the mastermind of a \$77 million fraud scheme was sentenced to 15 years in prison. From 2005 to 2010, the defendant owned and operated a clinic in Brooklyn that billed Medicare under three corporate names: Bay Medical Care PC, SVS

Wellcare Medical PLLC and SZS Medical Care PLLC (collectively, Bay Medical Clinic). The defendant and her employees at the Bay Medical Clinic paid cash kickbacks to Medicare beneficiaries and used the beneficiaries' names to bill Medicare for more than \$77 million in services that were medically unnecessary or never provided. The defendants billed Medicare for a wide variety of fraudulent medical services and procedures, including physician office visits, physical therapy and diagnostic tests.

- In April 2014, the office managers at URI Medical Service, PC, was sentenced to 12 months in jail and, along with the office manager of Sarang Medical, PC, was ordered to pay \$5.9 million in joint and several restitution. URI and Sarang purportedly provided physical therapy, electric stimulation treatment, and other medical services to Medicare beneficiaries. According to the indictment, from approximately March 2007 through May 2012, the office managers and their co-conspirators artificially increased demand for medical services by providing Medicare beneficiaries with free goods and services, such as massages, facials, lunches, gift cards, and recreational classes. They then submitted false claims to Medicare for medical services, such as office visits, physical therapy, lesion destruction, and electrical stimulation treatment, which were medically unnecessary, not provided, and otherwise did not qualify for reimbursement. Once the beneficiaries arrived at the clinics, they were required to give their Medicare numbers to staff and to see a doctor, regardless of medical need, in order to receive the free, non-medical inducements. The office managers acted as patient recruiters and were paid for referring beneficiaries to the clinics. Both pleaded guilty to conspiracy to commit health care fraud and both were excluded from participating in any federal health care programs; the URI office manager was excluded for 18 years and the Sarang office manager was excluded for 10 years.
- In May 2014, two individuals were indicted and charged with health care fraud, conspiracy to commit health care fraud, and illegal use of individually identifiable health information. Since 2008, the defendants allegedly engaged in a long-running scheme to submit false claims for DME to a government-sponsored organization for managed care in New York. The scheme involved the defendants using information for approved, in-network equipment providers to obtain approvals that were then used to secure payments on behalf of sham companies that the defendants set up. Companies believed to have been involved in the scheme submitted fraudulent claims to the managed care organization in amounts over \$13 million since 2008; the organization paid out over \$4 million in reimbursement of those claims.
- In May 2014, two defendants were indicted and charged with conspiracy to commit health care fraud, making false statements relating to a health care matter, falsification of records in a federal investigation and money laundering. Between approximately October 2009 and August 2012, the defendants owned and operated a series of medical clinics that were used to submit more than \$14.3 million in Medicare claims, of which \$5.3 million was paid. The indictment alleges that the majority of the claims were fraudulent because they were for services such as vitamin infusions, physical and occupational therapy, and diagnostic tests that were medically unnecessary, not provided, or otherwise not

reimbursable. The defendants also allegedly laundered the proceeds of the fraudulent scheme and falsified documents, which they then provided to Medicare auditors and FBI in order to conceal the fraudulent scheme.

Southern Louisiana (Middle and Eastern Districts of Louisiana)

- In May 2014, the two-year prosecution of a \$258.5 million dollar Medicare fraud scheme, involving seventeen defendants, concluded when the medical director, on the eve of trial, pleaded guilty to conspiracy to commit health care fraud and when one owner and one patient recruiter, following a week-long jury trial, were found guilty of conspiring to commit health care fraud, committing health care fraud, and conspiring to pay and receive kickbacks. The fraud scheme, which spanned seven years, involved billing Medicare \$258.5 million dollars for psychotherapy services that were either not provided or medically unnecessary at three partial hospitalization programs located in Baton Rouge, Louisiana and Houston, Texas. In the end, 17 individuals were charged, and all 17 individuals were convicted. To date, one owner has been sentenced to 102 months' imprisonment and the medical director has been sentenced to 86 months' imprisonment.

Tampa (Middle District of Florida)

- In October 2013, two defendants pleaded guilty to conspiracy to commit money laundering of over \$1.8 million. All of the money they planned to launder came from a rehabilitation therapy services fraud scheme. Using shell companies such as Ariguanabo Investment Group, Inc. and IRE Diagnostic Center, Inc., the defendants received and disbursed substantial proceeds stemming from fraudulent rehabilitation therapy services claims that had been submitted to Medicare through Renew Therapy Center of Port St. Lucie, LLC. They were sentenced in July 2014 to 24 months in prison each, and ordered to pay restitution of over \$1.8 million.
- In December 2013, a key operator of a rehabilitation therapy services clinic who had submitted over \$10.5 million in fraudulent reimbursement claims to Medicare pleaded guilty to conspiracy to commit health care fraud. Over \$10.5 million in fraudulent claims were submitted to Medicare through Renew Therapy Center of Port St. Lucie for therapy services that had not been legitimately prescribed or provided. The defendant helped operate the clinic and paid kickbacks to patient brokers and others to obtain and use Medicare beneficiary identifying information in the company's fraudulent claims. In July 2014, he was sentenced to 48 months in prison and ordered to pay restitution, jointly and severally, of over \$6.2 million.
- In January and February 2014, the leader and organizer of a \$28 million health care fraud scheme and a disbarred attorney who played a central role in the scheme each pleaded guilty to conspiracy to commit health care fraud. The leader of the fraud scheme also pleaded guilty to making a false statement relating to health care matters. The fraud involved numerous comprehensive outpatient rehabilitation facilities and outpatient physical therapy clinics as well as other entities that were used to submit over \$28 million

in fraudulent claims to Medicare. All of the claims sought reimbursement for therapy services that were not legitimately prescribed and not provided. The fraudulent claims resulted in payments of over \$14 million by Medicare. The disbarred attorney was sentenced in August 2014 to 70 months in prison and ordered to pay restitution, jointly and severally, of \$14.4 million. A third defendant, who was a straw owner of one of the clinics used in the fraud scheme and had previously pleaded guilty to conspiracy to commit health care fraud, was sentenced in March 2014 to 30 months in prison.

- In May 2014, the former president and owner of a rehabilitation therapy services clinic was charged with conspiracy to commit health care fraud and conspiracy to commit money laundering of health care fraud proceeds. The defendant pled guilty on October 27, 2014. The defendant allowed over \$2.5 million in fraudulent claims to be submitted through her clinic to Medicare seeking payment for rehabilitation therapy services that were not legitimately prescribed and not provided. Medicare paid approximately \$1 million in reimbursement on the claims. The defendant admitted paying kickbacks in exchange for Medicare beneficiary identifying information and falsified medical records that were used to submit and support the fraudulent billing.

Dallas (Northern District of Texas)

- In October 2013, a federal jury in Texas convicted two defendants of conspiracy to commit health care fraud and fourteen substantive counts of health care fraud for falsely billing for physician care plan oversight. A third defendant, a doctor and medical director of the company, pled guilty. The trial defendants owned and operated “A Medical,” a physician house call company that provided doctor visits to Medicare beneficiaries in their home. During the trial the government proved that all billing for care plan oversight was fraudulent, and that the patient visits and home certifications were fraudulent as well. The court found that the total intended loss amount was over \$11 million. That figure included the intended loss billed by A Medical, as well as all of the home health billing that stemmed from the fraudulent certifications. The judge sentenced the owners of the company to 262 months and 135 months in prison. The medical director received a 57 month prison sentence. All defendants were ordered to pay, jointly and severally, over \$9 million in restitution to CMS.
- In January 2014, a Texas jury convicted two defendants of conspiracy to commit health care fraud and seven counts of substantive health care fraud. The defendants owned and operated a DME company called “His Grace Medical Supplies and More” (HGMS). Over ninety percent of the claims submitted by HGMS were for adult incontinence supplies. HGMS purchased a list of Medicaid beneficiaries that it used to file fraudulent claims with Medicaid. Many of the patients did not need or receive the adult incontinence supplies billed to Medicaid by HGMS. In response to a Medicaid audit, HGMS falsified medical paperwork by forging patient and doctor signatures to make it appear as if the patients received the medical supplies and that a doctor had diagnosed the patient as being incontinent. HGMS billed Medicaid in excess of \$2.3 million for adult incontinence supplies.

- In January 2014, two defendants were sentenced to 72 months each for their roles in a conspiracy to commit Medicare fraud. The defendants were foreign medical school graduates who were unlicensed to practice medicine in the United States. Both defendants acted as physicians in a house call practice where no meaningful medical treatment was provided to patients. More than \$2.7 million was fraudulently billed to Medicare for the house visits and diagnostic testing that was never performed.
- In May 2014, after a seven-day trial, a jury in the Northern District of Texas found two defendants guilty of conspiracy to commit health care fraud for their roles in a \$4 million Medicare fraud scheme. One defendant was a doctor who certified hundreds of Medicare beneficiaries for home health care that was medically unnecessary and often never provided. The second defendant was the Director of Nursing at PTM Healthcare Services, Inc., a defunct home health care agency in Irving, Texas. The scheme involved the manipulation of patient medical records, which are essential to submit and receive funds for home health services rendered to Medicare beneficiaries in need of skilled nursing care. The jury also convicted this defendant for health care fraud and making false statements related to health care matters.
- In June 2014, two defendants were sentenced for their roles in fraudulently operating hyperbaric oxygen therapy companies in North Texas. Both defendants admitted that they defrauded Medicare by billing for multiple sessions in one day when in actuality only one “dive” was performed. The defendants were sentenced to 60 months each and ordered to pay restitution in the amount of \$1.5 million.
- In August 2014, a Dallas, Texas DME salesman was sentenced to 36 months in prison and ordered to pay \$1.3 million in restitution. The defendant pled guilty to one count of false statements relating to health care matters in connection with his practice of supplying therapeutic shoes and shoe inserts to individuals with diabetes. He routinely forged physician signatures, provided patients with off-the-shelf shoe inserts instead of the custom inserts billed, failed to obtain current and proper measurements, and in one case, billed for therapeutic shoes and shoe inserts on behalf of a double amputee. Between 2010 and 2013, the defendant caused claims totaling more than \$890,000 to be submitted to Medicare and \$440,000 to be submitted to Texas Medicaid. He admitted that he accurately and truthfully completed all of the requirements for less than 10 percent of these claims.

Chicago (Northern District of Illinois)

- In October 2013, defendant a pharmacist in Chicago was convicted in connection with a \$1.7 million fraud scheme. The evidence at trial revealed that defendant submitted to two private insurance companies over 600 false claims for the drug Procrit, using patients’ names, dates of birth, and insurance information without their authorization. After the defendant was initially indicted in this case on health care fraud charges, he created false documents—including forged prescriptions, forged patient receipts, and false invoices—to make the false claims look legitimate. In total, defendant was convicted after a jury trial

of six counts of health care fraud, three counts of aggravated identity theft, and one count of obstruction of justice.

- In December 2013, a grand jury returned an indictment charging the CEO of Mobile Doctors, a company that arranged for thousands of physician home visits in Illinois, Michigan, Indiana, Arizona, and Texas, and one of the Mobile Doctors physicians with health care fraud. According to the indictment, the charges stemmed from a Medicare fraud scheme regarding the billing of patient visits at inflated levels based on the CEO's beliefs about what would avoid audits, rather than on what physicians actually did during the visits, as well as the false certification of patients for home health services provided by home health agencies. From 2007 through August 2013, when the CEO was first charged by complaint, Medicare paid Mobile Doctors more than \$30 million for physician home visits, millions of which were the result of the fraud scheme, according to the indictment.
- In February 2014, a physician was arrested and charged by complaint with drug and health care fraud charges. In addition, agents executed a seizure warrant for approximately \$126,000 on his bank account. On August 27, 2014, the defendant was charged by information with participating in a health care fraud scheme, in violation of 18 U.S.C. § 1347, and with acquiring Schedule II controlled substances by fraud and misrepresentation, in violation of 21 U.S.C. § 843(a)(2). Approximately one week later, the defendant pled guilty at arraignment. As a part of the plea agreement, he admitted to engaging in a scheme to defraud Medicare out of at least approximately \$500,000, which spanned several years, from November 2011 through February 2014. Furthermore, he admitted to knowingly prescribing controlled substances to patients who he had never seen or examined, and who he knew had never been examined by a licensed medical professional.
- In May 2014, a grand jury sitting in the Northern District of Illinois charged an owner and three former employees of a now-closed Illinois hospice company, Passages Hospice, LLC, as well as the company itself, on federal health care fraud charges for engaging in an extensive scheme to obtain higher Medicare and Medicaid payments by fraudulently elevating the level of hospice care for patients. In many instances, the level of hospice care allegedly exceeded what was medically necessary or actually provided, including for some patients who did not have terminal illnesses or who were enrolled far longer than the required life expectancy of six months or less. The defendants are charged with fraudulently obtaining millions of dollars as a result of the scheme.

Highlights of Successful Criminal and Civil Investigations

In addition to the Medicare Fraud Strike Force matters summarized above, our respective Departments successfully pursued criminal and civil investigations in a wide range of other areas:

Medical Device Companies

- In October 2013, medical device manufacturer Boston Scientific and its Guidant subsidiaries agreed to pay \$30 million to settle civil FCA allegations that from 2002 to 2005, Guidant knowingly sold defective heart devices to health care facilities that in turn implanted the devices into Medicare patients. The settlement resolves allegations that two lines of Guidant's implantable defibrillators contained a defect that resulted in "arcing," which caused the device to short circuit. The government alleged that although Guidant took corrective action to fix the defects, the company continued to sell its remaining stock of the old, defective versions of the devices and took steps to hide the problem from patients, doctors and the FDA. In February 2010, Guidant pleaded guilty to criminal charges of misleading the FDA and failing to submit a labeling change to the FDA relating to the defective devices.
- In December 2013, medical device manufacturer Abbott Laboratories, Inc. agreed to pay \$5.5 million to resolve civil FCA allegations that the company caused health care providers to submit false claims to Medicare for surgical procedures involving the company's carotid and peripheral vascular stents and biliary stents. The government alleged that Abbott knowingly paid prominent physicians unlawful kickbacks with the expectation that these key physicians would arrange for the hospitals with which they were affiliated to purchase Abbott's vascular products for use in treating Medicare beneficiaries.
- In December 2013, medical device manufacturer Genzyme Corp. agreed to pay \$22.3 million to resolve civil FCA allegations relating to its marketing of an unapproved version of Seprafilm, a thin film used to prevent adhesions after surgery. The settlement resolves allegations that Genzyme sales representatives taught doctors and other staff to dissolve Seprafilm sheets in saline to create a "slurry" for use in laparoscopic or "key hole" surgeries by inserting a catheter filled with the mixture into the body and squirting it into the abdominal cavity. Seprafilm is FDA-approved for use in open abdominal surgery, but not for minimally invasive surgeries, such as laparoscopic or keyhole surgery. As a result of this conduct, Genzyme allegedly caused hospitals and other purchasers of Seprafilm to submit false and fraudulent claims to federal health care programs for uses of Seprafilm that were not reimbursable.
- In January 2014, CareFusion Corp. agreed to pay \$40.1 million to settle civil FCA allegations that it paid kickbacks and promoted its products for uses that the FDA had not approved. The settlement resolves allegations that CareFusion paid kickbacks to the physician co-chair of the Safe Practices Committee at the National Quality Forum, a non-profit organization that reviews, endorses, and recommends standardized health care

performance measures and practices; and that CareFusion knowingly promoted the sale of ChloroPrep for uses that the FDA had not approved, some of which were not medically accepted indications, and made unsubstantiated representations about the appropriate uses of ChloroPrep.

- In May 2014, medical device manufacturer Medtronic, Inc. agreed to pay \$9.98 million to resolve civil FCA allegations that the company paid kickbacks to induce physicians to use certain of the company's cardiac rhythm management devices, including pacemakers and defibrillators. The government alleged that Medtronic: (1) paid implanting physicians to speak at events intended to increase the flow of referral business; (2) gave physicians tickets to sporting events; and (3) developed marketing/business development plans for physicians at no cost.
- In August 2014, medical device manufacturer Smith & Nephew agreed to pay \$8.3 million to settle civil FCA allegations that the company violated the Trade Agreements Act by selling medical devices to the government that had been manufactured in Malaysia, when they were required to be manufactured in the United States.
- In August 2014, medical device manufacturer Omni Surgical L.P. (d/b/a Spine 360) and an Indiana spinal surgeon agreed to pay a combined \$2.6 million to settle civil FCA allegations that Spine 360 paid illegal kickbacks to the physician to induce him to use the company's products. The government alleged that payments made by Spine 360 to an entity controlled by the physician pursuant to a series of intellectual property agreements were actually shams, and that the payments were intended to compensate the physician for using Spine 360 products in his surgeries.

Pharmaceutical Companies

- In November 2013, pharmaceutical company Johnson & Johnson (J&J) and certain subsidiaries agreed to pay over \$2.2 billion to resolve criminal and civil allegations relating to the prescription drugs Risperdal, Invega, and Natrecor. In a criminal information, the United States alleged that Janssen Pharmaceuticals, Inc., a J&J subsidiary, marketed the antipsychotic drug Risperdal off-label to control behavioral disturbances in non-schizophrenic dementia patients at a time when the drug was approved only to treat schizophrenia. Janssen pleaded guilty to misbranding Risperdal in violation of the FDCA and paid criminal fines and forfeiture totaling \$400 million. In addition, J&J and its subsidiaries agreed to pay \$1.72 billion to resolve civil FCA allegations that they: (1) promoted Risperdal and Invega off-label to control behaviors in dementia patients, children, and the mentally impaired; made false statements concerning the drugs' safety and efficacy; and paid kickbacks to physicians; (2) paid kickbacks to long-term care pharmacy Omnicare to promote Risperdal and other J&J drugs in nursing homes and to switch patients to J&J's drugs; and (3) promoted Natrecor off-label for serial, scheduled outpatient infusions of patients with congestive heart failure.

- In February 2014, pharmaceutical company Endo Health Solutions Inc. and its subsidiary Endo Pharmaceuticals Inc. (Endo) agreed to pay \$192.7 million to resolve criminal and civil liability arising from Endo's marketing of the prescription drug Lidoderm for uses not approved by the FDA. During the relevant time period, Lidoderm was approved only for the relief of pain associated with post-herpetic neuralgia (PHN), a complication of shingles. However, the government charged that Endo introduced into interstate commerce Lidoderm that was misbranded because its labeling lacked adequate directions for use in the treatment of non-PHN related pain, including low back pain, diabetic neuropathy, and carpal tunnel syndrome. These uses were intended by Endo but never approved by the FDA. The resolution included a deferred prosecution agreement and forfeiture totaling \$20.8 million and civil FCA settlements totaling \$171.9 million.
- In March 2014, Israeli pharmaceutical company, Teva Pharmaceuticals USA Inc., agreed to pay \$27.6 million to settle civil FCA allegations that it and a subsidiary paid kickbacks to a Chicago psychiatrist. The United States alleged that the company, which manufactures the anti-psychotic drug clozapine, paid the psychiatrist kickbacks in the form of consulting and speaking fees in exchange for his agreement to prescribe clozapine to several thousand patients over an eight-year period. The United States also filed a civil suit against the psychiatrist which remains pending.
- In April 2014, pharmaceutical company Astellas Pharma, US, Inc. agreed to pay \$7.3 million to resolve civil FCA allegations relating to its promotion of the prescription drug Mycamine to treat pediatric patients, even though that use was not a medically accepted indication and, therefore, not covered by government health care programs.
- In September 2014, pharmaceutical company Shire Pharmaceuticals LLC agreed to pay \$56.5 million to resolve civil FCA allegations relating to its promotion of Adderall XR, Vyvanse and Daytrana (which are approved for the treatment of attention deficit hyperactivity disorder), and Pentasa and Lialda (which are approved for the treatment of mild to moderate active ulcerative colitis). The settlement resolves allegations that Shire (1) promoted Adderall XR for certain uses without clinical data to support such claims and overstated the drug's efficacy; (2) made false and misleading statements about the efficacy and "abuseability" of Vyvanse to physicians and state Medicaid formulary committees; (3) improperly marketed Daytrana, administered through a patch, as less abuseable than traditional, pill-based medications; and (4) promoted Lialda and Pentasa for off-label uses not approved by the FDA and not covered by federal health care programs, including the prevention of colorectal cancer.

Hospitals

- In January 2014, St. Joseph Health System, Inc., of London, Kentucky, agreed to pay \$16.5 million to resolve civil FCA allegations that it submitted false claims to federal health care programs for medically unnecessary cardiac procedures, including stents, pacemakers, and catheterizations. The settlement also resolved allegations of Anti-Kickback Statute (AKS) and Stark Law violations arising out of contractual relationships

between the hospital and the owners of Cumberland Clinic, the physicians' practice group alleged to have performed the unnecessary services.

- In March 2014, Halifax Hospital Medical Center, which operates a hospital and outpatient clinics in the Daytona Beach, Florida area, agreed to pay \$85 million to resolve civil FCA allegations that Halifax entered into certain prohibited contracts with oncologists and neurosurgeons in violation of the Stark Law. The government alleged that between 2004 and 2010 Halifax entered into employment contracts with neurosurgeons that greatly exceeded fair market value and varied with the volume and value of the referrals or other business generated. Further, Halifax allegedly entered into employment contracts with oncologists that included "operating margin" bonuses based on the volume or value of the referrals or other business generated by the physicians. The government alleged that because of the prohibited relationship between Halifax and these physicians, the claims that Halifax submitted for their referrals were false. This settlement followed a district court ruling granting the United States' partial summary judgment motion and finding that the Medical Center's contracts with the medical oncologists violated the Stark Law. As part of the settlement, Halifax entered into an enhanced CIA with HHS-OIG that includes requiring Halifax to retain an independent compliance expert to provide annual reviews of the effectiveness of its compliance program and to hire a legal independent review organization to review Halifax's contracts with physicians and other health care providers.
- In March 2014, Memorial Hospital, an Ohio nonprofit corporation that operates an acute care hospital in Fremont, Ohio, agreed to pay \$8.5 million to settle civil FCA allegations that it engaged in improper financial relationships with referring physicians in violation of the AKS and Stark Law. The settlement involved self-disclosed allegations that financial relationships that Memorial had with two physicians – a joint venture between Memorial and a pain management physician and an arrangement under which an ophthalmologist purchased intraocular lenses and then resold them to Memorial at inflated prices - violated statutory requirements.
- In May 2014, Ashland Hospital Corporation d/b/a King's Daughters Medical Center (KDMC), a Kentucky corporation based in Ashland, Kentucky, agreed to pay \$40.9 million to resolve civil FCA allegations that it billed for medically unnecessary coronary stents and diagnostic catheterizations performed on Medicare and Medicaid patients. The settlement also resolves allegations that KDMC violated the Stark Law by paying certain cardiologists salaries that exceeded fair market value. In addition to payment of the settlement amount, KDMC agreed to enter into a comprehensive 5-year CIA with HHS-OIG that includes enhanced provisions to address patient care issues and KDMC's relationships with referral sources.
- In July 2014, Community Health Systems, Inc., based in Franklin, Tennessee, and its affiliated hospitals (collectively, CHS) agreed to pay a total payment of \$98.2 million to resolve allegations that: (1) CHS knowingly admitted patients who presented to CHS hospital emergency departments as inpatients when they should have been treated as outpatients or provided observation care; (2) a CHS hospital, Laredo Medical Center,

presented false claims to Medicare for certain inpatient procedures that should have performed on an outpatient basis; and (3) CHS improperly billed Medicare for services referred to Laredo Medical Center by a physician who was offered a medical directorship at the hospital in violation of the Stark law.

- In August 2014, Arizona non-profit corporation Carondelet Health Network, d/b/a Carondelet St. Mary's Hospital and Carondelet St. Joseph's Hospital, agreed to pay \$35 million to resolve civil FCA allegations that the hospitals billed federal health care programs for inpatient rehabilitation facility services when an inpatient setting was not appropriate.

Physicians

- In November 2013, a cardiologist was sentenced to six-and-a-half years in prison and ordered to pay \$19 million in restitution after pleading guilty to charges of attempt and conspiracy to commit health care fraud and false or fraudulent claims. According to published reports, the physician-owner of two companies spent more than \$6 million in advertising on Spanish-language media to entice patients to visit his clinics. The New Jersey and New York clinics, Cardio Med Services LLC (Cardio-Med) and Comprehensive Health care & Medical Services LLC (Comprehensive), purported to provide cardiology, internal medicine, and other medical services to Medicare and Medicaid beneficiaries. During the visits, the physician-owner ordered and performed essentially the same diagnostic tests for nearly all the patients he treated, regardless of their symptoms. He also instructed his non-physician employees to order and perform diagnostic tests for patients of other doctors working at his companies, even though he had not examined those patients and the other physicians had not ordered the unnecessary tests. He admitted that he falsified patient charts and falsely diagnosed a majority of his patients with coronary artery disease and debilitating and inoperable angina to justify prescribing and administering unnecessary treatment, therefore subjecting them to serious risk of injury or death.
- In January 2014, the physicians' group Hematology and Oncology Center PLLC of Somerset, Kentucky, its oncologist owner, and its office manager agreed to pay \$2 million to resolve civil FCA allegations that they purchased non-FDA approved chemotherapy drugs at steep discounts from a foreign distributor known as Quality Specialty Products and submitted or caused the submission of false claims to Medicare for those drugs. The practice group and office manager pleaded guilty to misdemeanors under the FDCA and agreed to a voluntary exclusion from the Medicare program for six years.
- In March 2014, a licensed psychiatrist formerly employed by the Department of Veterans Affairs was sentenced to a year-and-a-half in jail and was ordered to pay \$1.2 million in restitution. According to court documents, the psychiatrist billed Medicare approximately \$4 million for home treatment of beneficiaries. However, many of those visits never occurred. On a number of occasions, he submitted claims to Medicare for home medical visits at locations within New York City, even though he was physically located in China

at the time of these purported home visits. Additionally, he submitted claims to Medicare for 55 home medical visits to beneficiaries who were hospitalized on the date of the purported visits. In addition to the sentencing, the psychiatrist was excluded from participating in any federal health care programs for 15 years.

- In April 2014, a doctor of osteopathic medicine who owned the dermatological practices AGS, Inc. and Central West Virginia Dermatology Associates, Inc., was sentenced to eight years and three months of incarceration and was ordered to pay \$265,330 in restitution and a \$2.6 million fine. Between May 1998 and June 2004, the doctor allegedly submitted false claims to Medicare and Medicaid and, as a result, he reached a settlement with the United States in August 2005 that included his voluntary exclusion from all federal health care programs for 10 years. According to the government, after his voluntary exclusion the doctor arranged an elaborate scheme to hide his involvement with his dermatology clinics and continue billing and receiving payment from Medicare and Medicaid, which included sham sales of the clinics. He later lied in Federal bankruptcy court, lied to a Federal investigator, stole the identity of another physician, and obstructed an IRS investigation. The doctor was convicted by a jury on charges of health care fraud, bankruptcy fraud, identity theft, and the filing of false tax returns.
- In April 2014, Hope Cancer Institute, Kansas-based practice, and its oncologist owner agreed to pay \$2.95 million to settle civil FCA allegations that they submitted false claims to federal health care programs for the administration of the cancer drugs Rituxan, Avastin, and Taxotere at higher dosages than were actually provided to the beneficiaries. As part of the settlement, the doctor agreed to a ten-year exclusion from all federal health care programs.
- In June 2014, a North Carolina physician pled guilty to criminal health care fraud and tax evasion and agreed to pay \$6.2 million to settle civil FCA allegations that he submitted claims to federal health care programs for medically unnecessary tests and procedures and for services never provided. The government alleged that the physician and his medical practice submitted claims for echocardiograms, allergy tests, hemorrhoidectomies, Enhanced External Counterpulsation (EECP) therapy and other tests and procedures that were never provided or, if provided, were not medically necessary.

Pharmacies

- In November 2013, Caremark L.L.C., a pharmacy benefit manager (PBM) operated by CVS Caremark Corporation, agreed to pay \$4.3 million to settle civil FCA allegations that it wrongfully avoided repayment for prescription drug costs that Medicaid incurred for beneficiaries who also were covered by private health insurance plans for whom Caremark administered prescription benefits. The government alleged that Caremark used a computer claims processing platform called “Quantum Leap” to deny claims for reimbursement submitted by Medicaid, which is the payer of last resort when the beneficiary is also covered by private insurance.

- In February 2014, long-term care pharmacy provider Omnicare, Inc. agreed to pay \$4.2 million to resolve civil FCA allegations that it knowingly caused false claims for the drug Aranesp to be submitted to federal health care programs. The settlement resolves allegations that Omnicare solicited and received kickbacks from the drug manufacturer Amgen Inc. in return for implementing “therapeutic interchange” programs designed to switch beneficiaries from a competitor drug to Aranesp. Amgen previously paid \$24.9 million to resolve allegations relating to payments to Omnicare and other pharmacies.
- In March 2014, Sears Holdings Corporation and Kmart Corporation (collectively, Kmart) agreed to pay \$3.3 million to settle allegations that Kmart offered and paid remuneration in the form of gift cards and coupons to beneficiaries of federal health care programs to induce the beneficiaries to transfer or fill their prescriptions at Kmart pharmacies. The government alleged that, as a result of this conduct, Kmart violated the FCA by submitting improper claims for payment to Medicare, TRICARE, the Veterans Affairs program, and Medicaid. Sears wholly owns Kmart, which operates retail stores containing pharmacies throughout the United States.
- In June 2014, long-term care pharmacy provider Omnicare Inc. agreed to pay \$124 million to resolve civil FCA allegations that it offered improper financial incentives to skilled nursing facilities to select Omnicare to supply drugs to elderly Medicare and Medicaid beneficiaries. The government alleged that Omnicare entered into below-cost contracts to supply prescription medication and other pharmaceutical drugs to skilled nursing facilities and their resident patients in order to induce the facilities to select Omnicare as their pharmacy provider.
- In September 2014, CVS Caremark agreed to pay \$6 million to settle civil FCA allegations that it failed to reimburse Medicaid for prescription drug costs paid on behalf of Medicaid beneficiaries who also were eligible for drug benefits under Caremark-administered private health plans. The settlement resolved allegations that CVS Caremark improperly deducted certain co-payments and deductible amounts from payments that Medicaid was entitled to receive, causing Medicaid to incur prescription drug costs that should have been paid for by the Caremark-administered private health plans.

Prescription Drug Fraud

- In October 2013, the manager and registered agent of Miami-Dade County based Greenwall Pharmacy Discount, Inc. (Greenwall Pharmacy) was sentenced to five years and three months of incarceration. The defendant and his co-conspirators paid recruiters to refer Medicare beneficiaries to Greenwall Pharmacy, where their Medicare numbers were used to file false claims for various health care benefits, primarily prescription drugs. The manager also purchased false invoices from a pharmaceutical wholesaler. Medicare Part D plan sponsors paid Greenwall Pharmacy approximately \$6.8 million in reimbursement for the false claims. In addition to his term in prison, the defendant was ordered to pay \$6.8 million in restitution after pleading guilty to conspiracy to commit health care fraud.

- In October 2013, National Respiratory Services, LLC (NRS), a Louisville-based mail-order pharmacy, was ordered to pay restitution in the amount of \$2 million for FDA violations and health care fraud. In July 2006, Medicare drastically reduced the reimbursement rate for compounded drugs to discourage companies from using those particular codes. On July 1, 2007, Medicare began denying all claims for inhalation compounded drugs, deeming them “medically unnecessary.” According to the indictment, NRS allegedly marketed directly to doctors who specialized in treating respiratory illnesses, and solicited business from these doctors to supply their patients with the drugs that the doctors prescribed to treat asthma, emphysema, and other respiratory illnesses. Between July 2006 and June 2008, NRS compounded drugs and then falsely represented that the drugs were FDA-approved when, in fact, these drugs were not FDA approved, were of various potencies, were non-sterile, and therefore were adulterated and misbranded. NRS was ordered to pay \$2 million in restitution, joint and several, after pleading guilty to health care fraud charges. NRS’s vice president and two pharmacists were all sentenced in connection with this case.
- In December 2013, a Kansas radiologic technician was sentenced to serve 39 years in prison and ordered to pay \$22,680 in restitution after pleading guilty to charges of tampering with a consumer product and fraudulently obtaining controlled substances. According to court documents, while employed at Hays Medical Center in Kansas in June 2010, the defendant became aware that he was infected with Hepatitis C. Notwithstanding that knowledge, he injected himself with syringes of the anesthetic fentanyl, which were intended for patients who were undergoing medical procedures. He added saline to the same syringes, which were then administered unknowingly by nurses to the patients. Consequently, instead of receiving the prescribed dose of fentanyl, the patients received saline that was tainted with the Hepatitis C virus. The defendant repeated this pattern of behavior at other hospitals where he worked, which investigators determined, caused at least 45 patients to become infected with Hepatitis C. Some of these patients experienced very serious health complications, including one death in which Hepatitis C was a contributing factor.
- In December 2013, a Philadelphia doctor was sentenced to 30 years in prison, ordered to forfeit \$200,000 and fined \$50,000 for operating a pill mill out of his clinic. The defendant was the physician owner of Family Medical Society, a division of Women’s Medical Society, Inc. (Women’s Medical Society). According to the indictment, the physician and his co-conspirators allegedly ran a “pill mill” out of Women’s Medical Society. His customers purchased prescriptions for controlled prescription drugs without any legitimate medical purpose. The United States charged that the defendant used his practice to distribute over 500,000 pills containing oxycodone, 400,000 pills containing alprazolam, and over 19,000 ounces of cough syrup containing codeine. Many of the illegal prescriptions and some office visits were paid for by Pennsylvania Medicaid, Medicare Part D, and other insurers.
- In February 2014, a resident of Allegheny County, Pennsylvania, was sentenced in federal court to six months imprisonment, six months of home confinement, three years of

supervised release, and forfeiture of \$56,000, on his conviction of unlawfully selling drug samples. The defendant met his supplier in various grocery store parking lots late at night to receive garbage bags filled with the samples. The samples had the lot numbers and expiration dates removed from the pill packaging making it impossible to know if the drugs had expired or had been recalled. Over the time period charged, the defendant collected a total of \$181,108.

- In August 2014, the leader of a \$20 million drug-diversion scheme was sentenced to eight years in prison and ordered to pay more than \$9 million in restitution. The sentence followed a February 2014 jury verdict against three defendants charged with participating in a conspiracy to defraud Medicare and Medi-Cal through the issuance of thousands of fraudulent prescriptions of anti-psychotic drugs out of a sham medical clinic in Glendale, California. The drugs would be filled at pharmacies by recruited beneficiaries and then returned to the clinic, where the drugs would be diverted to the black market, sold back to pharmacies, made to look like new bottles, and re-billed again in a repeating cycle. In November 2011, a total of 18 defendants were indicted in connection with the scheme, of which 16 have been convicted to date.

Medical Clinics

- In October 2013, the operator of several medical clinics in and around Houston, Texas, was sentenced to six years of incarceration and ordered to pay \$4.3 million in restitution, joint and several, after pleading guilty to conspiracy to commit health care fraud. The defendant had been excluded from participation in all Federal health care programs on the basis of an earlier health care fraud conviction in California. To conceal his involvement with the clinics, the operator registered the clinics in the names of other individuals, known as “straw owners,” including the mother of his child and employees at the clinics. According to court documents, he allegedly paid individuals to recruit Medicare beneficiaries, including some residing in homeless shelters, to visit the clinics to receive medically unnecessary diagnostic tests. He partnered with another individual, who acted as the “medical director” of the clinics, though he did not see or evaluate patients. The two conspirators then billed Medicare more than \$15 million for the unnecessary tests, using the second individual’s Medicare provider number. The co-defendant was sentenced to four years and four months in prison and ordered to pay \$6.9 million in restitution.
- In February 2014, two physicians who owned a chain of addiction treatment clinics and a clinical laboratory agreed to pay \$15.8 million to resolve civil FCA allegations relating to fraudulent urine testing. The government alleged that the lab (PremierTox 2.0 LLC) submitted false claims to federal health care programs for medically unnecessary quantitative urine drug tests referred to it by the treatment clinic (Addixion Recovery of Kentucky, LLC (d/b/a SelfRefind)). PremierTox allegedly misidentified the class of drug that was tested for and, as a result, obtained greater reimbursement than it was entitled to receive. As part of the settlement, the laboratory entered into a five-year CIA with HHS-OIG that obligates PremierTox to undertake substantial internal compliance reforms and commit to third-party reviews of claims submitted to federal health care programs.

- In March 2014, Valley Heart Consultants and two of its physicians agreed to pay \$3.9 million to settle civil FCA allegations that they billed Medicare for nuclear stress tests that were substandard and, in many cases, unnecessary. The government also alleged that the nuclear medicine used in the tests was injected by personnel who lacked the requisite license.
- In April 2014, CRC Health Corp. (CRC), a national substance abuse and mental health treatment provider, agreed to pay \$9.3 million to settle civil FCA allegations that it submitted false claims for substandard treatment of adult and adolescent Medicaid patients suffering from alcohol and drug addiction. The government alleged that CRC billed for substance abuse therapy services at New Life Lodge, its facility in Burns, Tennessee, that were not provided or were provided by therapists who were not properly licensed by the state of Tennessee. The government also alleged that CRC failed to make a licensed psychiatrist available to patients at New Life Lodge, failed to maintain required patient-staffing ratios, and exceeded the state-licensed bed capacity at the facility. In addition, the government alleged that CRC double-billed Medicaid for prescription substance abuse medications given to New Life Lodge residents.
- In May 2014, Massachusetts-based Calloway Laboratories, Inc. (Calloway Labs) agreed to pay \$4.7 million to settle civil FCA allegations that it submitted false claims in connection with unnecessary urine drug testing.

Dental Practices

- In October 2013, a Connecticut resident was sentenced to eight years and one month in jail and ordered to pay \$5.2 million in restitution after pleading guilty to charges of health care fraud and tax evasion. He had been excluded by HHS-OIG from participating in Federal health care programs (including Medicaid) partnered with a dentist to fraudulently open three dental practices in Connecticut. In the applications to enroll the entities as Medicaid providers, this defendant failed to disclose that he had an ownership interest in the dental practices, that he was the subject of prior disciplinary and criminal actions, or that he was excluded from the Medicaid program. He concealed his involvement in the dental practices by having other licensed dentists, including his business partner act as nominal heads of the clinics.

Medical Equipment and Supplies

- In October 2013, a Los Angeles-area church pastor was sentenced to 87 months in prison for conspiring to defraud Medicare. The defendant owned and operated the DME company Bonfee, Inc. His daughter owned and operated the DME company Ibon, Inc. According to the indictment, two other co-conspirators acted as marketers who solicited and obtained Medicare beneficiaries' information by offering them medically unnecessary medical equipment. The information was used by a physician and others to create fraudulent prescriptions and medical documents. The two DME owners then used the information to submit or cause the submission of more than \$11 million in false claims to

Medicare for power wheelchairs and other medical equipment that had not been provided or were medically unnecessary. Four of the conspirators previously pleaded guilty and were sentenced to a combined 14 years and nine months of incarceration and were ordered to pay joint and several restitution of \$6.3 million. The fifth was convicted at trial and is awaiting sentencing.

- In November 2013, the Richmond, Texas owner of a DME company was sentenced to four years in prison and ordered to pay nearly \$1.5 million in restitution following his conviction for conspiracy to commit health care fraud and health care fraud aiding and abetting. Spectrum Foundation, Inc. (Spectrum) was a Texas business that purportedly provided Medicare and Medicaid beneficiaries with orthotics and other DME. According to the indictment, Spectrum's owner and his co-conspirators used Spectrum to submit claims for DME that were medically unnecessary or were not provided at all and claims for DME that were intentionally miscoded. Spectrum then submitted claims to Medicare in excess of \$3.4 million for these and other items, including 157 unpaid claims on behalf of deceased beneficiaries. The owner also owned and operated an ambulance transportation company and submitted or caused the submission of claims to Medicare for ambulance services that had not been provided or for instances when the beneficiaries had been transported in a standard minivan.
- In February 2014, a Houston, Texas defendant was sentenced to 87 months in federal prison for his role in a multi-state health care fraud scheme involving unnecessary motorized wheelchairs. The defendant was ordered to pay restitution in the amount of \$1.6 billion to the Medicare and Medicaid programs and a fine of \$12,500. According to the indictment, from May 2002 to June 2003, the defendant conspired with others to defraud Medicare and Medicaid through the mass marketing of motorized wheelchairs. As part of the scheme, the defendant and his co-conspirators recruited Medicare and Medicaid beneficiaries and would secure the beneficiaries protected health information. The defendant and his co-conspirators created false medical necessity certificates, drafted prescriptions from doctors who had never examined those beneficiaries, and then billed Medicare for motorized wheelchairs. He then delivered less expensive scooters to the beneficiaries instead, and in other instances, did not deliver anything even though Medicare had paid for a motorized wheelchair.
- In April 2014, the owner and managing employee of Midvalley Medical Supply who also worked as an office manager under a different name at the Vermont Clinic in Los Angeles, was sentenced to six years and four months of incarceration and ordered to pay \$9.6 million in joint and several restitution. According to the indictment, the managing employee, along with a physician's assistant at the Vermont Clinic and others, recruited and transported Medicare beneficiaries to the Vermont Clinic, often with the promise of free, medically unnecessary DME. Some of these beneficiaries lived hundreds of miles away. The beneficiaries were often prescribed DME and underwent medically unnecessary tests, including nerve conduction tests and ultrasounds. The managing employee then used the patient information obtained from beneficiaries at the Vermont Clinic to bill for medically unnecessary DME prescriptions through her DME company,

Midvalley. In addition to her sentencing, the managing employee was excluded from participating in any federal health care programs for 30 years. The physician's assistant pleaded guilty to charges of health care fraud and conspiracy to commit health care fraud and is awaiting sentencing.

- In June 2014, following their convictions at trial, two Los Angeles area DME supply owners and a San Francisco based "recruiter" were sentenced to 144 months, 51 months, and one year and one day, respectively, for their roles in a \$3.2 million health care fraud and kickback conspiracy. A San Francisco physician and another recruiter, both of whom pled guilty and testified at trial, were sentenced to 24 months in prison and three years' probation, respectively. The lead defendants were also ordered to forfeit \$1,577,426 and pay restitution of the same amount to CMS. The investigation showed that from approximately December 2006 and continuing through July 2011, the owners submitted over 400 false and fraudulent power wheelchair claims to Medicare in the names of beneficiaries identified by recruiters using fraudulent prescriptions and medical records prepared by the physician. After the recruiters identified beneficiaries, the physician conducted sham examinations to obtain background information for the required Medicare paperwork and gave the information and bogus prescriptions to the owners. The owners paid the physician a \$100 kickback for each power wheelchair prescription.

Skilled Nursing Facilities

- In October 2013, the Ensign Group, LLC agreed to pay \$48 million to resolve claims that between 1999 and 2011, six of its skilled nursing facilities submitted false claims to the government for physical, occupational, and speech therapy services that were not medically necessary to treat the conditions of Medicare beneficiaries or were not provided. The Government also alleged that the Ensign facilities had a corporate culture that improperly incentivized therapists and others to increase the amount of therapy provided to patients to meet allegedly planned targets for Medicare revenue that were set without regard to patients' individual therapy needs and could be achieved only by upcoding and/or providing unnecessary services.
- In December 2013 and January 2014, two former executives of HealthEssentials Solutions, Inc., a now-defunct provider of primary medical care to patients in long-term care facilities, agreed to pay a combined \$1 million to resolve civil FCA allegations that between 1999 and 2004 they caused HealthEssentials to bill for services that were inflated or not medically necessary and pressured employees to conduct special medical assessments on patients without regard to whether the patients required the assessments, solely to increase the amount that HealthEssentials could bill for the visits. HealthEssentials and another executive previously pleaded guilty to criminal charges arising out of their role in the company's billing scheme.
- In June 2014, Foundation Health Services, its affiliated nursing facilities, and its President and Chief Executive Officer agreed to pay a combined \$750,000 to resolve civil FCA

allegations that they submitted false claims for payment to Medicare and Medicaid for materially substandard and/or worthless skilled nursing facility services.

Home Health Care

- In December 2013, five Miami, Florida based patient-recruiters were sentenced to a combined 20 years and 4 months in prison and ordered to pay a combined \$30.6 million in restitution. Caring Nurse Home Health, Corp. and Good Quality Home Health, Inc., were Florida-based businesses that purportedly provided home health care and physical therapy services to eligible Medicare beneficiaries. According to the indictment, the companies' presidents and co-conspirators allegedly paid kickbacks to individuals to recruit beneficiaries as patients. The companies then billed Medicare for home health services, including diabetic injections, skilled nursing visits, and physical therapy, which were not medically necessary and/or had not been provided. The defendants also sent patient recruiters and beneficiaries to doctors to obtain prescriptions for home health services that were not medically necessary. The two companies submitted about \$52.5 million in claims to Medicare for home health services purportedly provided to about 1,300 beneficiaries. The presidents of the two companies were previously sentenced to a combined 13 years and three months in prison and ordered to pay \$35 million in restitution.
- In January 2014, nine individuals were sentenced to a combined 26 years and 11 months of incarceration and ordered to pay a combined \$29.9 million in restitution, joint and several, for their connections to a Medicare fraud scheme. The owners of five home health companies, located in Oak Park, Michigan, and later Troy, Michigan, created fictitious therapy files, appearing to document physical and occupational therapy services provided to Medicare beneficiaries when, in fact, no such services were provided. According to court documents, the owners hired patient recruiters, who offered cash and the promise of prescriptions drugs to Medicare beneficiaries in return for their Medicare identification numbers. Physical therapists and physical therapist assistants at the companies used the Medicare information to create false physical therapy files using blank, pre-signed forms to make it appear as if physical therapy services had been rendered. The forms were then used to bill Medicare nearly \$20 million for services that had not been rendered and were medically unnecessary.
- In April 2014, Amedisys Inc. and its affiliates, a Louisiana-based for-profit company that is one of the nation's largest providers of home health services, agreed to pay \$150 million to resolve civil FCA allegations that they submitted false home health care billings to the Medicare program. The settlement resolved allegations that between 2008 and 2010 certain Amedisys offices improperly billed Medicare for ineligible patients and services. Amedisys allegedly billed Medicare for nursing and therapy services that were medically unnecessary or provided to patients who were not homebound, and otherwise misrepresented patients' conditions to increase its Medicare payments. Additionally, the settlement resolved certain allegations that Amedisys' financial relationship with a private oncology practice – whereby Amedisys employees provided patient care coordination

services to the oncology practice at below-market prices – violated the Anti-Kickback Statute and Stark Law. As part of the settlement, Amedisys agreed to enter into a comprehensive five-year CIA with HHS-OIG.

- In June 2014, four defendants involved in a home health care fraud scheme were sentenced to a combined 13 years and seven months in prison and were ordered to pay more than \$5.5 million in joint and several restitution. The defendants were a doctor of osteopathic medicine and medical director for the home health agencies Jackson Home Healthcare, Inc. (JHH) and Prestige Health Services, Inc. (PHS); the director of JHH; a registered nurse, PHS's director of nursing, and director of the home health agencies Houston Compassionate Care, Inc. (HCC) and Texas Comprehensive Healthcare Resources, Inc. (TCHR); and a local hospital worker. According to the indictment, the local hospital worker accessed hospital files without authorization and obtained personal health information of hospital patients, which he then provided to the director of JHH in return for payment. Employees of TCHR then used the stolen information to contact beneficiaries and solicit them for home health care services, including falsely stating that the beneficiaries' physicians referred them for a home health evaluation when, in fact, the physicians never made a referral, did not establish a plan of care, and were unaware that the beneficiaries were being contacted by a home health agency. JHH, PHS, and HCC billed Medicare more than \$12 million for home health services allegedly provided to beneficiaries who had been solicited. The services did not qualify for payment because the patients: (a) were not under the care of a physician who had established the plan of care, (b) were not confined to the home, and (c) were not in need of skilled nursing care.

Counseling

- In December 2013, a licensed professional counselor in Oklahoma was sentenced to 21 months in prison and ordered to pay \$147,184 in restitution for presenting false claims against the Medicaid Program for services not provided. The defendant pled guilty to presenting false claims to the Oklahoma Health Care Authority.
- In April 2014, two women who defrauded North Carolina Medicaid using stolen therapists' identities were sentenced in Charlotte, North Carolina. One defendant was sentenced to 111 months in prison and her co-conspirator was sentenced to 102 months, and they were both ordered to pay a combined \$10.1 million in restitution, jointly and severally. From 2008 to 2012, both defendants operated a series of afterschool and summer child care programs. They recruited juvenile Medicaid beneficiaries and their families to participate in the programs by promising that the programs would be free for Medicaid recipients. Thereafter, the defendants and others stole the Medicaid identification numbers of the children and used those numbers to submit false claims for mental health services that were never provided. The two also stole the identities of licensed and approved clinicians in order to submit the claims. One defendant was also excluded from participating in any federal health care program for 28 years. This was a joint investigation by the HHS-OIG, the IRS and the North Carolina Medicaid Investigations Division.

- In May 2014, a licensed professional counselor in Oklahoma was sentenced to three years of probation, ordered to complete 104 hours of community service, and ordered to pay \$98,003 in restitution for submitting false and fraudulent claims against the Medicaid Program for services not provided. From November 2009 through April 2011, the defendant claimed Medicaid reimbursement for behavioral counseling services for Medicaid-eligible children, which was never actually provided.

Managed Care Organizations

- In August 2014, the City of New York agreed to pay \$2 million to resolve civil FCA allegations that the New York City Human Resources Administration (HRA) caused various managed care organizations to provide health care coverage to individuals that were ineligible to receive Medicaid benefits through New York State's Medicaid program. As part of the settlement, HRA accepted responsibility for failing to timely review and close certain Medicaid cases after being provided information that those beneficiaries may have moved outside of New York City, and it admitted that its inaction caused one or more MCOs to receive payments to insure individuals who were ineligible for benefits through New York State's Medicaid program. HRA also agreed as part of the settlement to establish a process to investigate and close Medicaid cases whenever it learns that a Medicaid beneficiary no longer resides within its coverage area.

Chiropractic Services

- In May 2014, the owner of Sylmar Physician Medical Group, Inc., a chiropractic clinic located in a strip mall in San Fernando Valley, California, was sentenced to five years and three months in jail, was ordered to pay \$1 million in restitution, and had more than \$300,000 in assets seized. According to court documents, the owner billed Medicare for chiropractic manipulations purportedly provided to beneficiaries when, in fact, the treatments were either merely massages and not reimbursable by Medicare or were never actually provided. In an effort to conceal his fraud from HHS-OIG investigators, the owner falsely reported to the Los Angeles Police Department that he had been carjacked and that the requested patient files had been stolen. The owner billed Medicare more than \$1.7 million for purported chiropractic treatments between 2005 and 2012, for which he was paid more than \$1 million.

Physical Therapy

- In December 2013, three individuals doing business in Houston, TX locations as the Lymphedema & Wound Care Institute Inc. agreed pay \$4.3 million to settle civil FCA allegations that they submitted false claims for physical therapy treatments provided by unqualified therapists. The government alleged that from January 2006 through September 2012, the defendants billed the Medicare program for providing manual lymphatic drainage therapy using massage therapists as opposed to physical therapists, as required under Medicare rules and regulations. As part of the settlement, one of the individuals agreed to a 10-year exclusion from all federal health programs.

- In January 2014, contract therapy providers RehabCare Group, Inc. and RehabCare Group East, Inc. (collectively, RehabCare); Rehab Systems of Missouri (RSM); and management company Health Systems, Inc. (HSI) agreed to pay \$30 million to resolve civil FCA allegations that, between March 2006 and December 2011, RehabCare arranged with RSM to obtain RSM's contracts to provide therapy to federal health care program beneficiaries residing in 60 nursing homes controlled by RSM's majority owner and managed by HSI. In exchange for this stream of referrals, RehabCare allegedly paid RSM an upfront payment of as much as \$600,000, plus a percentage of the revenue generated by each referral.
- In March 2014, the co-owners of Flores Home Health Care Inc. were sentenced to a combined 12 years in prison and ordered to pay \$8.4 million in joint and several restitution for their involvement in the fraud scheme. From approximately October 2009 through June 2012, the co-owners of this Miami home health care agency billed Medicare and were paid approximately \$8 million for physical therapy and home health services that were not medically necessary and/or had not been provided.
- In April 2014, physical therapy clinics Alliance Rehabilitation, LLC and Active Physical Therapy Services, LLC agreed to pay \$2.8 million to settle civil FCA allegations that they submitted claims falsely representing that the physical therapy services being billed were either rendered or directly supervised by the physical therapist identified on the claims. In fact, the physical therapist identified on the claims allegedly had no involvement in the services rendered.

Hospice Care

- In November 2013, Hospice of the Comforter Inc. (HOTCI) agreed to pay \$3 million to resolve civil FCA allegations that it provided hospice services to patients who were not terminally ill and not eligible for the Medicare hospice benefit. Specifically, HOTCI allegedly directed its staff to admit all referred patients without regard to whether they were eligible for the Medicare hospice benefit, falsified medical records to make it appear that certain patients were eligible, employed field nurses without hospice training, established procedures to limit physicians' roles in assessing patients' terminal status and delayed discharging patients when they became ineligible for the benefit.
- In March 2014, CLP Healthcare Services, the parent company of Hospice Compassus, of Bretwood, Tennessee, agreed to pay \$3.9 million to settle civil FCA allegations that it submitted false claims for patients treated at its hospice facilities. The government alleged that Hospice Compassus was submitting false claims for hospice care for patients who were not eligible for such care.
- In May 2014, the operator of Home Care Hospice, Inc. (HCH), a for-profit hospice provider that purportedly provided hospice services for patients at nursing homes, hospitals, and private residences, in the Philadelphia, Pennsylvania area, was sentenced to 14 years and eight months in prison and ordered to pay \$16.2 million in restitution, joint

and several. According to the indictment, the operator and his co-conspirators billed Medicare more than \$14 million for alleged services provided by HCH, even though: (1) some patients were ineligible and inappropriate for hospice care; and (2) some services were billed at a higher reimbursement level, but still not provided to the patients. In order to increase HCH's patient census, the operator authorized payments to certain physicians and other health care professionals as an incentive to refer patients to HCH and to certify that they were appropriate for hospice care, even though they were not eligible. He also paid physicians and other health care professionals to serve as HCH medical directors, hospice physicians, and advisors when, in reality, the contracts for these positions were to mask payments for patient referrals. The operator directed employees to maintain ineligible patients who were not terminally ill on hospice care, in some instances for more than one year, and he authorized the fabrication of supporting documentation for patient files to substantiate approximately \$12.8 million in fraudulent claims billed to Medicare. The operator was found guilty by a jury on charges of conspiracy to commit health care fraud, health care fraud, money laundering, and mail fraud. Ten other defendants have been sentenced to a combined eight years in prison in connection with this scheme.

Identity Theft

- In December 2013, an undocumented alien residing in Wisconsin was sentenced to six months in prison and ordered to pay \$231,920 in restitution after pleading guilty to a charge of theft of government funds. The defendant falsely used the identifying information of another person to obtain federally funded health care benefits and Social Security disability benefits. From 2004 to 2009, she received health care items and services, including a liver transplant, for which Medicaid and Medicare collectively paid a total of \$165,463. From 2005 through 2011, she used the same false identity to fraudulently qualify for about \$66,457 in Social Security disability benefits, which she converted to her own use knowing she was not entitled to them.

Ambulance Transportation Fraud

- In November 2013, Filyn Corporation, the owner and operator of California-based Lynch Ambulance, paid more than \$3 million to resolve civil FCA allegations that from approximately 2001 through 2007, Filyn regularly billed Medicare and TRICARE for non-emergency, basic life support transports of beneficiaries who were not "bed-confined" at the time of transport or whose transports were otherwise not medically necessary.
- In November 2013, Pacific Ambulance, Inc. (Pacific) and Bowers Companies, Inc. (Bowers), both California ambulance companies, agreed to pay \$8 million to resolve civil FCA allegations that between 2004 and 2011, they entered into numerous below-cost contracts with skilled nursing facilities. The Government alleged that the contracts constituted prohibited "swapping" arrangements, wherein Pacific and Bowers offered prices to the skilled nursing facilities that were below their total costs of providing ambulance transport services in return for referrals of future Medicare business.

- In January 2014, a husband and wife team who owned and operated the Murfreesboro Ambulance Service (MAS) in Tennessee, were sentenced to a combined 12 years and one month of incarceration after being convicted by a jury on charges of conspiracy, Medicare fraud, making false statements related to health care matters, wire fraud, and aggravated identity theft. The defendants' ambulance company transported Medicare and Medicaid patients to and from dialysis treatments who were not qualified to receive ambulance transportation. According to evidence presented at trial, for more than a decade, the couple submitted and caused MAS to submit about \$1.2 million in false claims to Medicare and Medicaid. The claims falsely represented that beneficiaries were on stretchers when, in fact, they were actually transported in the front seat of the ambulance or in a seat in the back of the ambulance and that patients were transported individually when, in fact, two patients were transported simultaneously in one ambulance. To conceal the fraud, the husband and wife and their co-conspirators allegedly omitted facts and/or provided vague descriptions on records that were used to falsely bill Medicare. In addition to their prison sentences, they were also ordered to pay \$457,730 in restitution.
- In May 2014, the president and vice president of Alpha Ambulance, Inc., an ambulance transportation company located in Los Angeles, California, were sentenced to a combined 15 years and 3 months in jail and were ordered to pay \$1.6 million in joint and several restitution. According to the indictment, the defendants, along with their co-conspirators, provided ambulance transportation services to Medicare beneficiaries, knowing that their medical condition did not necessitate the transportation services. The co-conspirators instructed Alpha employees to document a reason justifying ambulance transportation services on run sheets even if a justification did not exist. Between June 2008 and July 2012, Alpha submitted approximately \$49 million in claims to Medicare for purported ambulance transportation and related services.
- In July 2014, the owner and operator of Penn Choice Ambulance Inc., an ambulance transportation company based in Philadelphia, Pennsylvania, was sentenced to eight years in prison and ordered to pay \$1.8 million in joint and several restitution. According to court records, the owner and her co-conspirators transported by ambulance Medicare beneficiaries who could walk or be safely transported by other means, falsely representing to Medicare that these patients required transportation by ambulance. The defendants also targeted and recruited patients who attended dialysis treatment, which is typically required three times per week, thereby allowing Penn Choice to bill extensively for these patients. To induce Medicare beneficiaries to be transported by Penn Choice even though such ambulance transport was not medically necessary, the defendants paid beneficiaries kickbacks of between \$100 and \$500 a month. Penn Choice billed Medicare approximately \$3.6 million for these false claims, which resulted in a more than \$1.5 million loss to Medicare. Three other defendants were sentenced to a combined nine years in prison in connection with this scheme.
- In August 2014, former Texas EMS officials were sentenced for their roles in a health care fraud conspiracy involving unnecessary ambulance services following their conviction after a jury trial in 2013. The former owners and operators of North East Texas EMS,

and, a supervisor employed by North East Texas EMS, carried out a scheme to defraud Medicare and Medicaid through the submission of false and fraudulent claims for nonemergency, scheduled, repetitive ambulance services which did not meet Medicare program coverage criteria. The owners were sentenced to imprisonment of 27 months, and 12 months and one day. Both were ordered to pay more than \$787,000 in restitution. The supervisor was sentenced to a five year term of probation with a condition requiring him to serve weekends in jail for the first year. He was also ordered to pay more than \$93,000 in restitution. The case was investigated by HHS-OIG, Texas Office of the Attorney General – Medicaid Fraud Control Unit, and the United States Department of Labor – Employee Benefits Security Administration.

Other Medicare/Medicaid Matters

- In February 2014, Diagnostic Imaging Group and its subsidiary, Doshi Diagnostic Imaging Service, P.C., agreed to pay \$15.5 million to resolve civil FCA allegations that the defendants billed federal health care programs for diagnostic tests that were not performed and/or not medically necessary and paid kickbacks to physicians in exchange for referrals.
- Between February and April 2014, three defendants involved in a health care fraud scheme were sentenced to a combined 14 years of incarceration and were ordered to pay more than \$2.1 million in restitution, joint and several. The defendants were the owner and Chief Executive Officer of New Century Adult Day Program Services, LLC; the Medicare provider and director at New Century; and an employee at New Century. According to evidence presented at trial, the defendants and their co-conspirators lured mentally disabled residents of local adult foster care homes, as well as people seeking narcotic drugs, to New Century with the promise that they could see a doctor who would prescribe them the narcotics they wanted if they signed up for New Century's psychotherapy program. New Century used the signatures and Medicare information of these individuals to claim that it was providing them psychotherapy when, in fact, it was not. Between March 2010 and April 2012, New Century billed Medicare approximately \$3.2 million for psychotherapy services. In addition to the sentencing, the three defendants were all excluded from participating in any federal health care programs for a combined 48 years.
- In March 2014, three defendants involved in a health care fraud scheme were sentenced to a combined 17 years and six months in jail and ordered to pay a combined \$3.5 million in joint and several restitution. One defendant owned and operated Helping Hands Youth and Family Services, a South Carolina business that purportedly provided rehabilitative behavioral health services to Medicaid beneficiaries. Her brother and his wife also worked in various management roles at Helping Hands. According to court records, Helping Hands management directed employees to fabricate and sign progress notes for mentoring services allegedly performed by other Helping Hands employees or former employees when, in fact, these services were not provided. Between January 2009 and October 2010, Medicaid paid more than \$8.9 million to Helping Hands for services

purportedly rendered. In addition to the sentencing, the three defendants were excluded from participating in any Federal health care programs for a combined 60 years. This case was worked jointly with the IRS and South Carolina Medicaid Fraud Control Unit.

- In May 2014, a licensed dietitian who owned and operated Hope Nutritional Services, LLC (HNS), of Brunswick, Georgia, was sentenced to 16 years in prison and ordered to pay \$4.3 million in restitution, joint and several. HNS purportedly provided nutrition services and counseling almost exclusively for children, most of whom were enrolled in the Government-funded Head Start program. A co-conspirator who was a licensed dietitian and owned and operated Quality Nutrition Services (QNS), pleaded guilty to one count of conspiracy and was ordered to pay \$159,273 in joint and several restitution. According to evidence presented at trial and at sentencing, from 2005 through 2011, the owner of HNS misappropriated the identities of thousands of children who were enrolled in Head Start programs located throughout the State of Georgia. Once she obtained the identities of these children, she fabricated patient files, falsified prescriptions from doctors, and submitted \$4 million worth of bogus claims to Medicaid for nutritional services that were not provided. As the co-conspirator, the owner of QNS allowed the submission of false and fraudulent claims under her provider number at QNS and transferred payment to the owner of HNS when Medicaid reimbursed her company. Both defendants were excluded from participating in any federal health care programs for a combined 50 years. This case was worked jointly with the FBI, Georgia Medicaid Fraud Control Unit, and the Georgia Department of Community Health.
- In August 2014, pharmaceutical distributor McKesson Corp. agreed to pay \$18 million to resolve civil FCA allegations relating to its shipping of vaccine provided under its contract with Centers for Disease Control and Prevention's Vaccines for Children Program. Specifically, McKesson allegedly failed to set temperature monitors included in the boxes at the ranges specified in the contract.
- In September 2014, a Glendale, California man, was sentenced to seven months in prison followed by seven months electronic home monitoring for his role in an expansive phantom provider fraud scheme, after pleading guilty to conspiracy to commit health care fraud in the District of North Dakota. According to court documents, the defendant caused over \$3 million in losses to the Medicare program over a period of approximately three years in which he supervised and managed a scheme that involved the creation of phantom medical providers across the United States. Conspirators hired foreign students who travelled to the United States on temporary J1 summer work/travel visas. Those students were employed to open up bank accounts and commercial mail boxes on behalf of phantom medical providers. Sometime after the students left the United States, members of the conspiracy used the fake providers to submit over \$13 million in fraudulent claims to Medicare. Medicare proceeds were laundered through check cashing businesses to disguise the recipients' identities. The defendant's case is set for a sentencing hearing on February 2015.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

A certain portion of the funds appropriated under HIPAA are, by law, set aside for Medicare and Medicaid activities of HHS-OIG. In FY 2014, the Secretary and the Attorney General jointly allotted \$199 million to HHS-OIG. Additionally, Congress appropriated \$28 million in discretionary funding for HHS-OIG HCFAC activities. Of these amounts, over \$14 million was sequestered in FY 2014 and thus unavailable to HHS-OIG to fight fraud and abuse in Medicare and Medicaid.

In FY 2014, HHS-OIG investigations resulted in 867 criminal actions against individuals or entities that engaged in crimes related to Medicare and Medicaid; and 529 civil actions, which include false claims and unjust-enrichment lawsuits filed in Federal district court, civil monetary penalties (CMP) settlements, and administrative recoveries related to provider self-disclosure matters. In addition, during FY 2014, HHS-OIG excluded a total of 4,017 individuals and entities, the details of which are below.

In FY 2014, HHS-OIG continued to staff and support Medicare Strike Force operations worked in conjunction with DOJ Criminal Division's Fraud Section, local USAOs, the FBI, and State and local law enforcement agencies. HHS-OIG has assigned agents to Strike Forces in Miami, New York City, Houston, Tampa, Detroit, Los Angeles, Southern Louisiana, Dallas, and Chicago. HHS-OIG has supported Strike Force operations by providing investigative, analytic, and forensic resources. These Strike Forces have effectively investigated and prosecuted individuals and entities that do not provide legitimate health care services, but exist solely for the purpose of defrauding Medicare and other Government health care programs. The continued support of Medicare Strike Force operations is a top priority for HHS-OIG.

Program Savings

Investigations, audits, and evaluations frequently reveal vulnerabilities or incentives for questionable or fraudulent practices in agency programs or administrative processes. As required by the Inspector General Act, HHS-OIG makes recommendations to agency managers to address these vulnerabilities. In turn, agency managers recommend legislative proposals or other corrective actions that, when enacted or implemented, close loopholes and reduce improper payments or conduct. The savings from these joint efforts toward program improvements can be substantial. For FY 2014, potential savings from legislative and administrative actions that were supported by HHS-OIG recommendations were estimated by third parties, such as the Congressional Budget Office or actuaries within HHS, to be \$15.7 billion – \$14.4 billion in Medicare savings and \$1.3 billion in savings to the Federal share of Medicaid.

Additional information about savings achieved through such policy and procedural changes may be found in the HHS-OIG fall Semiannual Report to Congress, on-line at <http://oig.hhs.gov>.

Exclusions

One important mechanism for safeguarding the care provided to program beneficiaries is through exclusion of providers and suppliers who have engaged in the abuse or neglect of patients or fraud from participation in Medicare, Medicaid, and other federal health care programs. During FY 2014, HHS-OIG excluded a total of 4,017 individuals and entities. Among these were exclusions based on criminal convictions for crimes related to Medicare and Medicaid (1,310) or to other health care programs (432); for patient abuse or neglect (189); or as a result of licensure revocations (1,744). This list of conduct is not meant to be exhaustive, but identifies the most prevalent causes underlying HHS-OIG's exclusions of individuals or entities in FY 2014. In addition to those mentioned in the Program Accomplishments section above, exclusion actions by HHS-OIG included:

- California – A physician was excluded from federal health care programs for a minimum period of 35 years on the basis of her conviction on counts of wire fraud, mail fraud, tax evasion, and witness tampering. The physician was sentenced to 14 years of incarceration and her license to practice as a medical doctor was suspended indefinitely by the Medical Board of California. According to court documents, she concocted a product that she labeled, described, and promoted under several different names. She and her employees falsely claimed that the product could cure or treat many human diseases and conditions, including cancer, and falsely represented that the product was made of herbs from around the world and that the product was manufactured according to the needs of each patient. She caused the product to be shipped to customers throughout the United States, and customers traveled to her facility to receive treatment. Depending on the purported product strength, the physician charged between \$750 and \$4,270 for about a week's supply. In reality, her product did not have the represented cancer cure rate, was not made of herbs from around the world, and was not manufactured by her in a laboratory for each patient. She was also suspended indefinitely from participation in the California Medi-Cal program.
- Pennsylvania – A physician was excluded for a minimum period of 20 years on the basis of his conviction for conspiracy to distribute controlled substances and distribution of controlled substances. According to court documents, from about January 2005 to about September 2010, the physician sold controlled substances and prescriptions for controlled substances to cash-paying customers outside the usual course of professional practice and with no legitimate medical purpose. He purchased the controlled substances from pharmaceutical supply companies and had the drugs shipped to his office, where he packaged the drugs into small boxes for resale to his customers. He falsified "medical" records to make it appear as if his customers received medical exams and treatment. The physician was sentenced to seven years of incarceration, and the Pennsylvania State Board of Medicine suspended his license to practice medicine for at least 10 years. Additionally, he was indefinitely precluded from participating in the Pennsylvania Medicaid program.
- Texas – A specialist in neurological surgery was excluded based on the revocation of his medical license to practice in the State of Texas, for so long as his license remains

revoked. The Texas Medical Board revoked his license after finding that his treatment of several patients represented a pattern of failing to follow appropriate preoperative planning standards and failing to recognize and respond to complications during surgery and postoperatively. One patient suffered complications from surgery performed by the specialist that resulted in excessive blood loss and quadriparesis. Another patient suffered a complication of retroperitoneal hemorrhage that was not addressed by the specialist. A third patient suffered excessive blood loss during surgery and had bone removed unnecessarily, which resulted in injury to the vertebral artery. Those issues led to a series of events that included a stroke, which ultimately resulted in the patient's death. The specialist also failed to manage severe post-operative complications suffered by a fourth patient, including an esophageal injury and a retained sponge, which was evident during an early post-operative x-ray.

- Oregon – An anesthesiologist was excluded for a minimum period of 50 years based on his conviction of 11 counts of first-degree sexual abuse and one count of first-degree rape. From about September 2007 to about July 2011, he engaged in sexual contact and sexual intercourse with patients who were incapacitated and under the influence of anesthetics at the time. The anesthesiologist was sentenced to 23 years and four months of incarceration, and his medical licenses were permanently surrendered and revoked in the States of Oregon and California, respectively.
- New York – A physician was excluded for a minimum period of 50 years based on his conviction for conspiracy to commit health care fraud and health care fraud. From about March 2005 to about July 2010, the physician participated in a scheme in which cash kickbacks were paid to Medicare beneficiaries to induce them to receive medically unnecessary physician services, physical therapy, and diagnostic testing. The physician was sentenced to 12 years and seven months of incarceration and was ordered to pay approximately \$50 million in restitution, joint and several. In addition, his licenses to practice medicine in New York and New Jersey were both revoked, and the New York State Office of the Medicaid Inspector General excluded him from participation in Medicaid.

Civil Monetary Penalties

HHS-OIG has the authority to impose civil monetary penalties (CMPs) against providers and suppliers who knowingly submit false claims to the Federal government, who participate in unlawful patient referral or kickback schemes, who fail to appropriately treat or refer patients at hospital emergency rooms, or who engage in other activities prescribed in statute. HHS-OIG continues to pursue its affirmative enforcement actions under these authorities. Examples include:

- New York – Henry Schein, Inc., a medical and dental equipment supplier, agreed to pay more than \$1.1 million to resolve allegations under the Civil Monetary Penalties Law (CMPL) provisions applicable to kickbacks. HHS-OIG alleged that Henry Schein, Inc., awarded customers, who were members of its Medical Privileges Program, points for

every item purchased electronically through the company and allowed customers to redeem those points for an array of items, including travel, hotel stays, iPads, gift cards, toasters, toys, and medical office products and supplies. However, HHS-OIG alleged that this type of remuneration was improper and did not qualify as a “discount” or “rebate” under the anti-kickback statute.

- Louisiana – Humana, Inc., agreed to pay \$1.8 million for allegedly violating the CMPL. HHS-OIG contended that Humana improperly submitted prescription drug event claims to the Medicare Part D program that included sales tax from Louisiana pharmacies, despite the fact that Medicare Part D drugs were not taxable under Louisiana law as of July 1, 2006. This case represents the first CMPL settlement with a Medicare Part D plan.
- North Carolina – Carolinas Medical Center (Carolinas) agreed to pay \$50,000 to resolve its liability under EMTALA. HHS-OIG alleged that Carolinas failed to provide an appropriate medical screening examination or stabilizing treatment to a patient who arrived at its emergency department with complaints of homicidal ideation and acute depression. The patient also stated that he feared harming himself and his wife and that he had visual hallucinations. The patient had visited Carolinas approximately two weeks earlier with similar complaints, at which time Carolinas learned the patient had access to firearms. Following a cursory examination, the patient was discharged from the emergency department with a prescription for a mild anti-depressant, and, shortly after discharge, the patient killed his wife, two of his four children, and himself.
- Texas – Medicus Laboratories, LLC agreed to pay \$5 million for allegedly violating the CMPL. HHS-OIG contended that Medicus submitted claims to Medicare that it knew or should have known were false by: (1) using Modifier 59 to bill for multiple units of a particular drug test when applicable rules only permitted for a single unit to be billed per patient encounter; and (2) billing for certain urinalysis codes when the testing was for screening purposes only and was not medically reasonable and necessary. In addition to payment of the settlement amount, Medicus agreed to enter into a five-year CIA with HHS-OIG. This settlement was the result of a cooperative effort between HHS-OIG’s Office of Audit Services and its Office of Counsel to the Inspector General as part of a cross-component initiative focusing on the urine drug testing industry.
- Texas – CVS Pharmacy, Inc. agreed to pay more than \$1.2 million for allegedly violating the CMPL. HHS-OIG contended that CVS Pharmacy knowingly presented or caused to be presented false or fraudulent claims by billing both Medicare Part B and Medicare Part D plan sponsors for immunosuppressant drugs provided to the same beneficiary on the same date of service.

Audits and Evaluations

The focus of HHS-OIG’s audits and evaluations is determined through a dynamic process and adjustments are made to HHS-OIG’s work plan throughout the year to meet priorities and to anticipate and respond to emerging issues with the resources available. HHS-OIG assesses

relative risks in Medicare and Medicaid (as well as the hundreds of other programs for which HHS-OIG has oversight authority) to identify the areas most in need of attention and, accordingly, to set priorities for the sequence and proportion of resources to be allocated. In assessing this relative risk, HHS-OIG considers a number of factors, including:

- mandatory requirements for HHS-OIG reviews, as set forth in laws, regulations, or other directives;
- requests made or concerns raised by Congress, HHS management, or the Office of Management and Budget (OMB);
- top management and performance challenges facing HHS;
- work to be performed in collaboration with partner organizations;
- management's actions to implement our recommendations from previous reviews; and
- timeliness.

As a consequence of this work planning process, HHS-OIG identified questionable or improper conduct in Medicare and Medicaid, and recommended corrective actions that, when implemented, will return misspent funds and prevent future wasteful or improper payments. Among HHS-OIG's audit and evaluation findings in FY 2014 were the following:

Full Vials of Herceptin

HHS-OIG found that most payments that Medicare contractors made to providers for full vials of Herceptin, a drug used to treat breast cancer that has spread to other parts of the body, were incorrect and included overpayments of about \$24.2 million. On nearly all of the incorrect line items, the providers reported the units of service for the entire content of one or more vial(s), each containing 440 mg of Herceptin, rather than reporting the units of service for the amount actually administered.

Medicare Administrative Contractors (MACs)

Through statements of work, CMS assigns functions to MACs and outlines performance standards for those functions. Performance standards include timeliness requirements for appeals, clean audits of financial management, and an effective strategy for medical reviews. HHS-OIG found that MACs did not meet all quality control standards, or had not resolved all unmet standards, and that CMS did not require action on all unmet standards.

Medicare Advantage Organizations (MAOs)

CMS requires that MA organizations have effective procedures to compile and report statistics regarding utilization, health status, operational costs, and other matters. Although CMS regularly reviews data that MAOs submit pursuant to Medicare Part C reporting requirements, its follow-up and uses of the data are limited.

Medicare Part D Sponsors

More than half of Part D sponsors did not voluntarily report data on potential fraud and abuse and, further, 28 percent of sponsors did not report performing any corrective actions in response to incidents of potential fraud and abuse between 2010 and 2012.

Beneficiaries Not Lawfully Present in the United States

HHS-OIG identified \$91.6 million in improper payments on behalf of unlawfully present beneficiaries in Part A and Part B during CYs 2009 through 2011. For the same period, HHS-OIG estimated \$29 million in unallowable gross drug costs on behalf of unlawfully present beneficiaries in Part D.

Incarcerated Beneficiaries

HHS-OIG identified nearly \$33.6 million in improper payments made on behalf of incarcerated beneficiaries in Part A and Part B during CYs 2009 through 2011. In addition, HHS-OIG estimated that CMS accepted PDE records with gross drug costs totaling an additional \$11.7 million for incarcerated beneficiaries in Part D for CYs 2006 through 2010.

Medicare Lump Sum Payments

Expanding the window of time covered by Medicare's lump sum payments for inpatient care would result in cost savings; HHS-OIG reviewed outpatient services that the admitting hospitals provided during the 11 days prior to the existing window and found that in 2011 Medicare and its beneficiaries paid an estimated \$263 million for such services.

Adverse Events

An estimated 22 percent of Medicare beneficiaries experienced adverse events during skilled nursing facility (SNF) stays; an additional 11 percent experienced temporary harm events during SNF stays. Physician reviewers determined that 59 percent of the adverse events and temporary harm events were clearly or likely preventable.

Hospitalization of Nursing Home Residents

In FY 2011, nursing homes transferred one-quarter of their Medicare residents to hospitals for inpatient admissions and Medicare spent \$14.3 billion on these hospitalizations. High rates of hospitalizations by individual nursing homes could signal quality problems within those homes.

Inappropriate Use of HIV Drugs

HHS-OIG found that almost 1,600 Medicare Part D beneficiaries had questionable utilization patterns for HIV drugs in 2012. Medicare paid \$32 million for HIV drugs for these beneficiaries. These beneficiaries had no indication of HIV in their medical histories, received an excessive dose or supply of HIV drugs, received HIV drugs from a high number of pharmacies or prescribers, or received contraindicated drugs. These patterns may indicate that a beneficiary is receiving inappropriate drugs and diverting them for illegal sale, that a pharmacy is billing for drugs that beneficiary never received, or that a beneficiary's identification number was stolen.

Coupons as Improper Inducement to Purchase Drugs

Pharmaceutical manufactures may not use copayment coupons to induce the purchase of drugs paid for by federal health care programs, including Medicare Part D. HHS-OIG found that manufacturers' current safeguards may not prevent all copayment coupons from being used for drugs paid for by Part D, and that Part D plans and other entities cannot identify coupon use within pharmacy claims.

Ambulatory Surgical Services Payment Differential in Medicare

HHS-OIG found that Medicare and beneficiaries could save \$12 billion during CYs 2012 through 2017 if CMS reduces hospital outpatient department payment rates for ambulatory surgical center (ASC)-approved procedures to the same level as ASC payment rates. In addition, Medicare could generate savings of as much as \$15 billion for CYs 2012 through 2017 if CMS reduces outpatient department payment rates for ASC-approved procedures to ASC payment levels for procedures performed on beneficiaries with low-risk and no-risk clinical needs.

Drug Dispensing and Supplying Fee Payment Rates

HHS-OIG found that Medicare Part B would have saved more than \$100 million in 2011 if dispensing fees for certain inhalation drugs and supplying fees for certain immunosuppressive drugs had been aligned with the rates that Part D or State Medicaid programs paid.

Improper Payments for E&M Services

HHS-OIG found that Medicare inappropriately paid \$6.7 billion for claims for E/M services in 2010 that were incorrectly coded and/or lacking documentation, representing 21 percent of Medicare payments for E/M services that year. E/M services are 50 percent more likely to be paid for in error than other Part B services and most improper payments result from errors in coding and from insufficient documentation.

Post-Acute Care Transfers

Medicare inappropriately paid hospital inpatient claims subject to its postacute care transfer policy, resulting in overpayments totaling approximately \$19.5 million over four years. Medicare overpaid the hospitals because the Common Working File edits related to postacute care transfers were not working properly.

Electronic Health Record (EHR) Fraud Vulnerabilities

Although EHR technology may make it easier to commit fraud, CMS and its contractors have not adjusted their practices for identifying and investigating fraud in EHRs. Furthermore, only about one quarter of hospitals had policies on the use of the copy-paste feature in EHR technology, which, if used improperly, could pose a fraud vulnerability.

Inefficient Residential Habilitation Payments

HHS-OIG found that payment rates for residential habilitation services provided at State-operated residences did not meet the Federal requirement that payment for services be consistent with efficiency and economy. For State FY 2010, Federal Medicaid payments exceeded actual costs for providing these services by approximately \$320 million (57 percent more than actual costs). Further, the payment rate for supervised residential habilitation services at State-operated residences was more than double the average rate for privately operated residences that offered the same services.

High Payments to Dentists

HHS-OIG identified 23 general dentists and six orthodontists in New York with questionable billing and who represented extreme outliers. Medicaid paid the providers \$13.2 million for pediatric dental services in 2012.

Unsupported Medicaid Matching Funds

The Maryland Medicaid program obtained Federal Medicaid funds for FYs 2009 through 2011 that were not supported by net expenditures. The State agency obtained \$12.9 billion in Federal Medicaid funds, but CMS awarded the State agency only \$12.8 billion for Medicaid expenditures. Maryland inappropriately withdrew the difference of \$115.3 million.

Incorrect Application of the Medicaid Federal Matching Assistance Percentage

The Massachusetts Medicaid agency did not always use the correct Federal medical assistance percentages (FMAPs) when processing claim adjustments. As a result, the State agency received approximately \$106 million (Federal share) more than it was entitled to. The State agency used incorrect FMAPs because it processed adjusted claims as current expenditures for both public and private providers.

Impermissible Health Care Related Tax

Pennsylvania's Gross Receipts Tax on Medicaid managed care organizations appeared to be a health-care-related tax that is impermissible for Medicaid funding. Through this tax, Pennsylvania collected \$1.8 billion from its Medicaid managed care organizations over three years and used that money to pay some of its share of capitation payments.

Other HHS-OIG Fraud and Abuse Prevention Activities

HCFAC funding also supported HHS-OIG's continued enhancement of data analysis and mining capabilities for detecting health care fraud, including tools that allow for complex data analysis. The HHS-OIG continues to use data mining, predictive analytics, trend evaluation, and modeling approaches to better analyze and target the oversight of HHS programs. Analysis teams use near-time data to examine Medicare claims for known fraud patterns, identify suspected fraud trends, and to calculate ratios of allowed services as compared with national averages, as well as other assessments. When united with the expertise of HHS-OIG agents, auditors, and evaluators, as well as our HEAT partners, HHS-OIG's data analysis fosters a highly effective combination of technologies and traditional skills to the fight against fraud, waste, and abuse.

Industry Outreach and Guidance

Advisory Opinions

Central to the HIPAA guidance initiatives is an advisory opinion process through which parties may obtain binding legal guidance as to whether their existing or proposed health care business transactions run afoul of the Anti-Kickback Statute, the CMP laws, or the exclusion provisions. During FY 2014, the HHS-OIG, in consultation with DOJ, issued 15 advisory opinions. A total of 314 advisory opinions have been issued during the 18 years of the HCFAC program.

Corporate Integrity Agreements

Many health care providers elect to settle their cases before litigation. As part of the settlements, providers often agree to enter into Corporate Integrity Agreements (CIA) with HHS-OIG to avoid exclusions from Medicare, Medicaid, and other federal health care programs. Under a CIA, a provider commits to establishing a program and taking other specified steps to ensure future

compliance with Medicare and Medicaid rules. The compliance programs are designed, in part, to prevent future fraud. HHS-OIG monitors providers' compliance with these agreements. HHS-OIG may impose penalties on entities that fail to comply with the requirements of their CIAs, as shown in the examples below:

Tennessee – CSHM, LLC, formerly known as FORBA Holdings and Church Street Health Management (CSHM), agreed to be excluded for five years based upon its alleged material breaches of its CIA. CSHM manages and operates the national chain of Small Smiles Dental Centers, which provides services primarily to children on Medicaid. CSHM's corporate predecessor entered into the CIA in 2010 as part of the resolution of a FCA case involving allegations that the company provided dental services to children on Medicaid that were medically unnecessary or failed to meet professionally recognized standards of care.

This exclusion marked the culmination of a series of alleged failures by CSHM and its corporate predecessors to comply with its CIA. Since the 2010 settlement, HHS-OIG had repeatedly cited CSHM and taken actions to address alleged violations of the CIA, including imposing stipulated penalties and forcing the divestiture of one of CSHM's clinics. Despite these actions, CSHM remained in material breach of its CIA, and HHS-OIG issued Notices of Intent to Exclude to the company in December 2013 and January 2014. Specifically, HHS-OIG found that CSHM had, among other things, failed to report serious quality-of-care reportable events, take corrective action, or make appropriate notifications of those events to the State dental boards, as required by the CIA. Although CSHM represented to HHS-OIG that it would cure the material breaches, HHS-OIG determined through meetings with CSHM and its Board of Directors and review of its written submissions that CSHM had failed to cure the material breaches and proceeded with the exclusion.

Florida – HHS-OIG imposed stipulated penalties totaling \$15,000 against Exactech, Inc., based upon the device manufacturer's failure to comply with certain requirements of its CIA. Specifically, Exactech failed to: (1) timely screen new "Covered Persons" to ensure they were not excluded or otherwise ineligible to participate in the federal health care programs; (2) distribute revised policies and procedures to "Covered Persons" whose job functions related to those policies and procedures; and (3) provide copies of Exactech's Code of Conduct and Anti-Kickback Statute policies and procedures to parties entering into new or renewed agreements with Exactech.

Florida – HHS-OIG imposed stipulated penalties totaling \$5,000 against American Sleep Medicine, Inc. (ASM) based upon its failure to satisfy certain reporting requirements under its CIA. Specifically, ASM failed to timely notify HHS-OIG of two incidents involving probable violations of the Anti-Kickback Statute that had been reported to ASM's internal compliance hotline.

Centers for Medicare & Medicaid Services

In FY 2014, CMS was allocated \$13.5 million by HHS, and appropriated \$237.3 million in discretionary funds by Congress to support its comprehensive program integrity strategy for Medicare, Medicaid and the Children's Health Insurance Program (CHIP). With these funds, CMS is working to ensure that public funds are not diverted from their intended purpose: to make accurate payments to legitimate entities for allowable services or activities on behalf of eligible beneficiaries of federal health care programs. CMS also performs many program integrity activities that are beyond the scope of this report because they are not funded directly by the HCFAC Account or discretionary HCFAC funding. Medicare Fee-for-Service error rate measurement and activities, Recovery Audit activities, and prior authorization initiatives are discussed in separate reports, and CMS will submit a combined Medicare and Medicaid Integrity Program report to Congress later this year.

CMS' approach is guided by four major principles that support the strategic goal of improving program integrity:

1. Prevention
2. Detection
3. Transparency and Accountability
4. Recovery

1. Prevention

Moratoria

Building on strong anti-fraud efforts already underway in the home health provider and ambulance supplier arenas, CMS in July 2013 announced the first use of its temporary moratoria authority granted by the Affordable Care Act. The moratoria stops the enrollment of new home health and ambulance enrollments in Medicare, Medicaid and the Children's Health Insurance Program (CHIP) in fraud "hot spot" areas of the country with demonstrated oversupply of certain types of providers. In January 2014, CMS extended the original enrollment moratoria for these locations and expanded to include HHAs in Broward county Florida, the Michigan counties of Wayne, Macomb, Monroe, Oakland, and Washtenaw and the Texas counties of Dallas, Collin, Denton, Ellis, Kaufman, Rockwall, Tarrant, Harris, Brazoria, Chambers, Fort Bend, Galveston, Liberty, Montgomery, and Waller. CMS also expanded the moratorium on ground ambulance suppliers in the Philadelphia area at the same time. All of these moratoria actions were extended an additional six months with the latest notice effective July 2014. The focus of these efforts is to prevent and deter fraud, waste, and abuse in problematic services and areas across the country while ensuring beneficiary access to care.

Under the moratoria, existing providers and suppliers can continue to deliver and bill for services, but no new provider and supplier applications will be approved in these areas, allowing CMS and its law enforcement partners to remove bad actors from the program while blocking provider entry or re-entry into these already over-supplied markets. CMS is required to re-evaluate the need for such moratoria every six months.

One Program Integrity

In FY 2014, CMS continued making improvements and changes to One Program Integrity (One PI), CMS' centralized portal that provides CMS contractors and law enforcement with a single access point to Medicare data as well as analytic tools to review the data. CMS moved from an integration contractor to a system support contractor while continuing to enhance the existing analytic tools. One PI improves CMS' ability to detect fraud, waste, and abuse with consistent, reliable, and timely analytics.

One PI users have access to the CMS Integrated Data Repository (IDR) to perform data analytics. The IDR contains a comprehensive and accurate set of Medicare provider, beneficiary and claims data from Medicare Parts A, B, and D back to January 2006. The IDR includes claims data at three distinct points in the claim life-cycle: at the time the claims are enumerated, the time claims are adjudicated, and at the time the claims have payment data posted. This access allows users to perform pre-payment analytics on historical data and develop models that can be applied in CMS' predictive analytics system, the Fraud Prevention System. With claims available from 2006, ZPICs will also be able to improve their analytics for post-payment detection of fraud, waste, and abuse.

In order to streamline access for our law enforcement partners, CMS transitioned STARS, a healthcare fraud, waste, and abuse analytics tool to the One PI suite tools in 2013. The One PI team is also replacing on-site instructor led training with virtual instructor led training to reduce training costs and provide better access to training for law enforcement

Compromised Number Checklist

Since January 2010, CMS has maintained a national database of compromised Medicare beneficiary and provider ID numbers called the Compromised Number Checklist (CNC). This database is populated by monthly submissions from CMS program integrity contractors. The purpose of the CNC is to share compromised ID numbers and any associated corrective actions that have been taken among CMS staff and contractors. CMS uses this national CNC database to enhance efforts to detect and prevent fraud and abuse in Medicare.

The compromised numbers list is updated on an ongoing, real-time basis by the PSCs/ZPICs and MEDIC.

The Command Center

CMS opened its state-of-the-art Command Center on July 31, 2012 to facilitate improvements in health care fraud detection and investigation, drive innovation, and help reduce fraud and improper payments in the Medicare and Medicaid programs. CMS is using the Command Center to collaborate in unprecedented ways with the private sector, law enforcement, and our State partners. The Command Center's advanced technologies and collaborative environment allow multi-disciplinary teams of experts and decision makers to more efficiently coordinate policies and case actions, reduce duplication of efforts, and streamline fraud investigations for more immediate administrative action. These collaborative activities enable CMS to take administrative actions, such as revocations of Medicare billing privileges and payment suspensions, more quickly and efficiently.

In FY 2014, the Command Center conducted 40 missions that included participants from CMS and our partners, including the HHS-OIG and FBI that are designed to lead to improvements in the fraud prevention and detection process. Missions are facilitated collaboration sessions that bring together experts from various disciplines to improve the processes for fraud prevention in Medicare and Medicaid. CMS is also working with FBI, HHS-OIG and other Federal agencies in the Command Center to pool resources to tackle cross-cutting issues surrounding fraud prevention.

DME Initiatives

DME suppliers pose a high risk of fraud to the Medicare Program and CMS has undertaken an aggressive strategy to address this risk. Through the DME Stop Gap Project, initiated in 2009, ZPICs/PSCs have increased site visits and interviews of DME suppliers, providers, and beneficiaries receiving DME products in high billing areas for DME supplies and products. In FY 2014, these additional funds supported DME investigations which included site visits to, and interviews of, suppliers, doctors and patients that were identified as potentially suspicious or high risk.

Correct Coding Initiative

In FY 2014, CMS continued to work with states to fully and correctly implement the Medicaid NCCI methodologies in their Medicaid programs, to add new Medicare and Medicaid NCCI edits to the quarterly Medicaid NCCI edit files, and to update the technical guidance document for states.

State Readiness

Today's modern design of IT systems encompasses the use of current technologies that span across the entire Medicaid Enterprise. These systems work in concert with one another and must adhere to certain regulations and guidance including the Medicaid Information Technology Architecture (MITA) framework; and, the Seven Standards and Conditions. Adhering to these mandates will promote consistency of business and technical processes, and IT platforms as well as standards across the Medicaid Enterprise.

The project includes independent technical assistance for IT and policy requirements, including monitoring and oversight, in working with state-specific system requirements, IT system builds, and associated interfaces for all states and the territories. All fifty states and the territories received technical assistance with moving through the Enterprise Life Cycle (ELC) Gate Review Process including any associated consults. States received assistance with project management, implementation and operations. Technical artifacts required by statute were analyzed and tracked to assess state progress. Gap analyses were done on a regular basis and risk registers were studied to identify opportunities for improvement.

2. Detection

Strengthened Program Integrity Activities in Medicare Advantage and Medicare Part D

In FY 2014, the National Benefit Integrity (NBI) MEDIC received on average approximately 591 actionable complaints per month; processed 39 requests for information from law enforcement per month; and referred an average of 40 cases to law enforcement per month. NBI MEDIC

referrals have resulted in restitution of \$33,680,679; forfeitures of \$6,925,049; and \$50,000 in civil settlements. The NBI MEDIC was responsible for assisting the HHS-OIG and DOJ, through data analysis and investigative case development, in achieving 54 convictions, 26 arrests, and 36 indictments. One particular pharmacy fraud case resulted in the arrest, indictment, and conviction of a Pennsylvania physician, pharmacist and more than 50 other individuals—including office staff, pseudo-patients, Medicare patients, and drug dealers in a large prescription drug conspiracy.

The physician was sentenced to 25 years in prison for distribution of a controlled substance resulting in death from his pill mill operation. The pharmacist was sentenced to 72 months of imprisonment and three years of probation. This case was predicated on information that the physician was identified for prescribing a high volume of controlled substances. He prescribed over 46,800 units of controlled substances, which equaled 84 percent of his total prescribed medications. The investigation revealed the physician worked with drug traffickers who recruited large numbers of pseudo-patients. With the help of his office staff, those “patients” were transported to his medical office for cursory examinations. The patients paid an office visit fee, usually \$150, by cash, check, or money order. The physician wrote prescriptions for them to obtain oxycodone-based drugs without a legitimate medical purpose and outside the usual course of professional practice. The patients were driven to a particular pharmacy, to have their prescriptions filled. The drugs were then turned over to the drug dealers so their organizations could sell the narcotics to other drug dealers who resold the drugs on the street.

In FY 2014, the Outreach and Education (O&E) MEDIC facilitated the CMS Parts C & D Fraud Waste and Abuse (FWA) training sessions which offer Medicare Advantage organizations and Prescription Drug plans an opportunity to collaborate and discuss techniques on how to prevent and detect fraud, waste, and abuse in the Medicare Advantage and Part D programs. These FWA training sessions are designed to educate Medicare Advantage organization and Prescription Drug plan staff through enhanced collaboration, information sharing, data analytics and communication. FWA training session stakeholders include plan sponsors, Pharmacy Benefit Managers (PBMs), representatives from law enforcement agencies—including HHS-OIG, U.S. DOJ, and other state and local law enforcement entities. These FWA training sessions provide a forum for stakeholders to learn about the most recent fraud schemes and fraud prevention best practices to assist in developing effective fraud prevention programs.

The O&E MEDIC is also responsible for many other outreach activities in 2014. In March, the CMS-Center for Program Integrity released its most comprehensive fraud fighting tools to date, the Medicare Advantage and Part D Fraud Handbook: Practical Techniques and Approaches on Detecting and Preventing Fraud, and an Online Training Module for Medicare Advantage organizations (MAOs) and Part D sponsors. The handbook is a modular online reference providing MAOs and Part D sponsors with industry best practices regarding processes, methods, and resources to support fraud prevention, detection, corrective action, preliminary investigation, and referral activities. The training is an online presentation covering each chapter of the Fraud Handbook in an on-demand webcast format.

Through rulemaking finalized in 2014, CMS will require that physicians and eligible professionals who write prescriptions for covered Part D drugs must be enrolled in Medicare, or

have a valid record of opting out of Medicare for their prescriptions to be covered under Part D. This requirement will help CMS ensure that Part D drugs are only prescribed by qualified individuals. This provision is effective December 1, 2015.

Marketing Surveillance Activities

CMS also strengthened program integrity in MA and Part D through marketing surveillance activities and compliance actions based on surveillance activities. In FY 2014, CMS conducted marketing surveillance activities, such as secret shopping and examining newspaper ads for unreported marketing events and content. These activities have improved plan sponsor oversight of marketing and lessened incidents of agent/broker misconduct.

Secret Shopping

Secret shopping provides undercover surveillance of formal Medicare Advantage (MA), Medicare Advantage and Prescription Drug (MA-PD), and prescription drug provider (PDP) marketing events. Plan sponsors report formal sales/marketing events to CMS from which contractors and CMS identify a sampling of events to secret shop. Shoppers use a CMS developed tool to facilitate and electronically record their evaluations of marketing events' compliance with CMS requirements. The tool is designed to capture various compliance aspects of the representatives' or agents' presentations, actions and provided materials. Additionally, it collects general information about the event, such as the number of people in attendance, the type of venue where the event was held, and the language in which the agent presented the event.

For the 2014 Annual Enrollment Period (AEP), CMS completed 1,320 secret shopping events. Of the events shopped, 1,133 (85.5 percent) had no validated deficiencies and were considered entirely compliant with Medicare regulations.

Of the 101 parent organizations shopped, 42 (or 41.6 percent) had no validated deficiencies noted. These 42 parent organizations represented 211 shops or approximately 16 percent of the total completed shops. Ninety-one (nearly seven percent) of the completed shops were presented in a language other than English, including:

- 65 events presented in Spanish;
- 18 events presented in Cantonese or Mandarin;
- four events presented in Korean;
- two events presented in both English and Spanish;
- one event presented in English, Spanish, and Mandarin/Cantonese; and,
- one event presented in English, Spanish, and Tagalog.

Compliance Actions Based on Surveillance Activities

CMS issues the following types of letters to sponsors who have had deficiencies related to our surveillance:

- Technical Assistance Letters (TAL) (not formal compliance notices);
- Notices of Non Compliance (NONC);

- Warning Letters with a Request for Business Plan; and,
- Ad-hoc Corrective Action Plans (CAPs).

To determine the appropriate action for deficiencies identified by secret shopping, CMS developed an objective, data-driven, and performance-based model. This model not only automated the review process, but also accounted for the seriousness of each deficiency to develop proper compliance action for identified deficiencies. Within this model, CMS categorized each deficiency and assigned a weighted value: administrative errors (one point), errors of omission (two points), undue beneficiary influence or harm (four points), and marketing misrepresentations (six points). To determine a plan sponsor’s overall performance score (OPS), CMS added the total number of points for all shops for each plan sponsor and divided by the total number of shops conducted for that plan sponsor.

The following three tables provide additional information on our process and findings. The first table shows how the OPS score is determined, while the second table is CMS’ tool to determine what type of compliance action should be issued based on the OPS score. Finally, the Compliance Action table provides a break out of the types of compliance actions taken and how many of each action were taken.

$\frac{\text{Total \# of deficiency points for all shops}}{\text{Total number of shops conducted}} = \text{OPS}$
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OPS Ranges and Corresponding Compliance Actions

Overall Shopping Performance Score Range	Compliance Action Taken
0.01 – 1.49	Technical Assistance Letter
1.50 – 3.49	Notice of Non-Compliance
3.50 – 6.99	Warning Letter with Business Plan
7.00+	Ad-hoc CAP

Compliance Actions Taken by Risk Level for Secret Shopping

Action ^b	High	Medium	Low	Total
Technical Assistance Letter	105	72	13	108
Notice of Non-Compliance	2	1	1	6
Warning Letter	2	0	0	0
Total Letters Issued	109	73	14	114

The unreported marketing events initiative is an attempt to determine if plan sponsors appropriately reports and represented their sales events activity to CMS. Daily and weekly print publications in U.S. domestic markets nationwide, including advertisements in several non-English languages are reviewed. CMS conducted reviews of 4,743 Medicare advertisements representing more than 16,000 total advertised events.

Of those advertisements reviewed, CMS identified 298 marketing events that were unreported, indicating a deficiency for each plan sponsor that had failed to submit a marketing event. Based on the results, CMS issued 16 TALs and six NONCs to plan sponsors related to unreported marketing events. NONCs were issued to plan sponsors that incurred deficiency rates of five percent or higher.

Medicare Advantage Encounter Data Processing System Contract

The Medicare Advantage (MA) Encounter Data Processing System (EDPS) is currently being maintained and modified out of guidance published in the final FY 2009 inpatient prospective payment system (IPPS) rule. In that rule, CMS revised regulations to clarify that CMS has the authority to require MA organizations to submit encounter data for each item and service provided to MA plan enrollees. Consistent with this authority, CMS is requiring MA organizations to submit encounter data for dates of service January 3, 2012 and later. MA plans are required to submit data for all institutional, professional and DME services provided to MA plan enrollees on or after that date.

Over the past several years there has been dramatic growth in the Medicare Advantage program. Today, one-fourth of Medicare beneficiaries are enrolled in Medicare Advantage plans. CMS pays Medicare Advantage organizations approximately \$145 billion per year for the care provided to these 15 million beneficiaries.

To better ensure that CMS is a more prudent purchaser, in January 2012 agency launched an initiative to collect encounter data from Medicare Advantage organizations. The encounter data detail each item and service provided to enrollees of Medicare Advantage organizations. These records are comparable in format and detail to claims submitted to the MACs by FFS providers. The encounter data collected by EDPS will allow CMS to recalibrate the risk adjustment payment model, so that MA payments more accurately reflect the demographics, patterns of care, and the predicted costs of diseases for MA enrollees. Recalibrating the model on MA diagnoses and expenditures, rather than using the FFS experience, will result in payments that are more accurate to MA organizations. CMS would also be able to evaluate coverage, profile and analyze service utilization, assess quality of care, with the goal of reducing fraud, waste and abuse and improving Medicare programs and healthcare in general.

CMS will use encounter data to determine the risk adjustment factors used to adjust payments, as required under CMS regulations at 42 CFR §422.304, to update risk adjustment models, to calculate Medicare Disproportionate Share Hospital percentages, for Medicare coverage purpose and to conduct quality review and improvement activities.

Medicaid/CHIP Financial Management Project

Under this project, funding specialists, including accountants and financial analysts, worked to improve CMS's financial oversight of the Medicaid program and CHIP. In FY 2014 through the continued efforts of these specialists, CMS removed an estimated \$2.4 billion (with approximately \$727 million recovered and \$1.7 billion resolved) of approximately \$10.7 billion identified in questionable Medicaid costs.

Furthermore, an estimated \$228 million in questionable reimbursement was actually averted due to the funding specialists' preventive work with states to promote proper state Medicaid financing. The funding specialists' activities included reviews of proposed Medicaid state plan amendments that related to reimbursement; development of financial management reviews; research regarding state Medicaid financing policy and practices; collaboration with states to resolve the Medicaid and CHIP portions of the A-133 "Single State" audits; and identification of sources of the non-Federal share of Medicaid program payments to ensure proper financing of Medicaid program costs.

HHS-OIG Hotline Database

CMS and its contractor use the HHS-OIG Hotline database to perform program integrity activities. Specifically, the contractor currently receives and processes the complaints HHS-OIG refers to CMS. CMS with the contractor resolves issues assigned through the HHS-OIG hotline.

3. Transparency and Accountability

Healthcare Fraud Prevention Partnership

One of the Secretary's key health care fraud prevention initiatives is to establish an ongoing partnership with the private sector to fight fraud across the health care system. Data collected and shared across payers can assist payers in evaluating trends, recognizing patterns consistent with potential fraud, and potentially uncover schemes or bad actors they could not otherwise identify using only their own information. Such collaboration is the purpose of the Healthcare Fraud Prevention Partnership (HFPP) which brings together both public and private, federal and state-level individuals and organizations combatting health care fraud across all payers.

The legal authority for the Partnership is 42 U.S.C. § 1320a-7c. The delegated authority allows for the Partnership to consult with, and arrange for the collection of data from, and sharing of data with representatives of health plans under the HCFAC program.

CMS added additional partners to the HFPP and is targeting further expansion of the partnership to include additional willing public and private payers once the technical and legal components of the program are in place. The increase in members providing data will increase the resources necessary for the trusted third party contractor to process and store the increased number of claims data from the new members.

The studies currently underway and listed below are the first conducted since receiving approval through Paperwork Reduction Act.¹¹

Study 2, Iteration 2: Non-Operational Providers:

The objective of this study is to create an aggregate list of non-operational provider entities for use in investigations. Possible impact includes stopping payments to non-operational providers after confirmation and referring providers to law enforcement.

Study 5: Urine Drug Screens:

The objective of this study is to identify providers who may be billing qualitative and quantitative urine drug screens inappropriately. Payers will be asked to provide claims billing data by provider for the qualitative and quantitative urine drug screens. Possible impact includes identifying cases for medical review, potential for edit development, overpayment collection, and referrals to law enforcement.

Study 1, Iteration 2: Misused Codes and Fraud Schemes:

The objective of this study is to share information on misused codes and fraud schemes to improve overall awareness of fraud patterns and trends. Possible impact includes recovering overpayments, referring providers to law enforcement, and closing vulnerabilities.

Improper Payment Error Rate Measurement and Increased Accountability in Medicaid and CHIP Programs

The Improper Payments Information Act (IPIA) of 2002, amended by the Improper Payments Elimination and Recovery Act of 2010 (IPERA), amended by the Improper Payments Elimination and Recovery Improvement Act of 2012 (IPERIA) requires each agency to periodically review programs it administers, identify programs that may be susceptible to significant improper payments, estimate the amount of improper payments, submit those estimates to Congress, and report on actions the Agency is taking to reduce improper payments.

The Medicaid program and CHIP have been identified as at risk for significant improper payments. To comply with the IPIA, IPERA and IPERIA, CMS established the Payment Error Rate Measurement program (PERM) to estimate improper payment error rates in Medicaid and CHIP. The error rates are based on reviews of the fee-for-service (FFS), managed care, and eligibility components of Medicaid and CHIP in the fiscal year under review. CMS measures Medicaid and CHIP error rates using a 17-state rotation so that each state is reviewed once every three years. After several years of development, the PERM error rate was published for the first time in FY 2008.

CMS reported in the FY 2014 Agency Financial Report the national Medicaid error rate that is based on measurements that were conducted in FYs 2012, 2013, and 2014. The FY 2014 national Medicaid error rate is 6.7 percent, representing \$17.5 billion in estimated improper payments compared to the FY 2013 improper payment rate of 5.8 percent or \$14.4 billion in improper

¹¹ Other studies conducted by the HFPP include Study 3–Revoked and Terminated Providers and Study 4–High Risk Pharmacy.

payments. The national component error rates are as follows: Medicaid FFS – 5.1 percent, Medicaid managed care – 0.2 percent, and Medicaid eligibility – 3.1 percent. The major cause of error in fee-for-service was state claims processing systems not being fully compliant with new requirements. These new requirements include: all referring or ordering providers must be enrolled in Medicaid, states must screen providers under a risk-based screening process prior to enrollment, and attending providers must include their National Provider Identifier on all electronically filed institutional claims. While these requirements will ultimately strengthen Medicaid’s integrity, they require systems changes that many states have not fully implemented.

Section 601 of the Children’s Health Insurance Program Reauthorization Act of 2009 (CHIPRA) prohibited HHS from calculating or publishing any national or state-specific error rates for CHIP until six months after a new PERM final rule was effective. In addition, Section 205(c) of the Medicare and Medicaid Extenders Act of 2010 exempted HHS from reporting a 2011 CHIP improper payment rate. On August 11, 2010, as part of enhanced efforts to reduce improper payments in federal programs, HHS issued the final regulations that fully implemented improvements to the PERM program. HHS commenced CHIP error rate reporting in FY 2012 and, therefore, CMS reported the first baseline CHIP error rate in the FY 2014 Agency Financial Report as all three cycles of states have now been reviewed.

CMS reported in the FY 2014 Agency Financial Report the national CHIP error rate that is based on measurements that were conducted in FYs 2012, 2013, and 2014. The FY 2014 national CHIP error rate is 6.5 percent, representing \$0.6 billion in estimated improper payments. The national component error rates are as follows: CHIP FFS–6.2 percent, CHIP managed care–0.2 percent, and CHIP eligibility–4.2 percent. The main sources of error are beneficiaries found to be ineligible for CHIP and errors related to state claims processing systems.

CMS is currently measuring cycles that will be reported in FYs 2015 and 2016.

Error Rate Measurement and Increased Accountability in Medicare Advantage (Part C) and Medicare Prescription Drug Benefit Program (Part D)

In compliance with IPJA, as amended by IPERA and IPERIA, CMS has implemented a systematic plan regarding improper payments for Part C and D programs. Unlike Medicare fee-for-service, CMS makes prospective, monthly per-capita payments to Part C organizations and Part D plan sponsors. Each per-person payment is based on a bid amount, approved by CMS, that reflects the plan's estimate of average costs to provide benefit coverage to enrollees. CMS risk-adjusts these payments to take into account the cost associated with treating individual beneficiaries based on health status. In addition, certain Part D prospective payments are reconciled against actual costs, and risk-sharing rules set in law are applied to further mitigate plan risk.

The Part C payment error estimate reported for FY 2014 (based on calendar year CY 2012) is 9.0 percent, or \$12.2 billion. The Part C payment error estimate has decreased from the FY 2013 estimate of 9.5 percent or \$11.8 billion. The Part C payment error is driven by errors in risk adjustment data (clinical diagnosis data) submitted by Part C plans to CMS for payment purposes. Specifically, the Part C payment error estimate reflects the extent to which diagnoses that plans

report to CMS are not supported by medical record documentation.

In an effort to improve the Part C error rate, CMS has implemented two key specific corrective actions described below: contract level audits and new regulatory provisions.

- **Contract-Level Audits:** HHS is proceeding with the RADV contract-level audits to recover overpayments. RADV verifies, through medical record review, the accuracy of enrollee diagnoses submitted by MA organizations for risk adjusted payment. RADV audits are HHS's primary corrective action to recoup improper payments. HHS expects that payment recovery will have a sentinel effect on the quality of risk adjustment data submitted by plans for payment. HHS expects to conduct RADV audits for approximately 30 MA contracts annually. RADV audits of payment year 2011, which began in FY 2014, will be the first HHS reviews to recoup funds based on extrapolated estimates.
- **New Regulatory Provisions:** In CMS-4159-F, "Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Program" (79 FR 100), HHS codified the Affordable Care Act requirement that MA organizations must report and return overpayments that they identify. In CMS-1613-FC, "Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Physician-Owned Hospitals: Data Sources for Expansion Exception; Physician Certification of Inpatient Hospital Services; Medicare Advantage Organizations and Part D Sponsors: CMS-Identified Overpayments Associated with Submitted Payment Data" (79 FR 66769), HHS also established a payment recovery and appeal mechanism to be applied when HHS identifies erroneous payment data submitted by an MA organization.

The Part D payment error estimate reported for FY 2014 (based on CY 2012) is 3.3 percent, or \$1.9 billion. The FY 2014 Part D error estimate represents the combined impact on Part D payments of four sources of error: Payment error related to low income subsidy status; payment error related to Medicaid status; payment error related to prescription drug event data validation; and payment error related to direct and indirect remuneration.

In an effort to improve the Part D error rate, CMS has implemented two key specific corrective actions described below: outreach to plan sponsors and new regulatory provisions.

- **Outreach:** Formal outreach to plan sponsors will continue for invalid/incomplete documentation.
- **New Regulatory Provisions:** HHS codified the ACA requirement that Part D sponsors must report and return overpayments that they identify. CMS also proposed a payment recovery and appeal mechanism to be applied when CMS identifies erroneous payment data submitted by a Part D sponsor.

Probable Fraud Measurement Pilot

There is no reliable estimate of the amount of fraud in the Medicare program. Documenting the baseline amount of fraud in Medicare is of critical importance, as it allows officials to better evaluate the success of ongoing fraud prevention activities. In collaboration with the HHS Office

of the Assistant Secretary for Planning and Evaluation (ASPE), CMS developed the methodology for the first nationally representative estimate of the extent of probable fraud in the Medicare fee-for-service program in FY 2011. In FY 2012, CMS developed the measurement tools for the pilot, and collaborated with government partners, including ASPE, on the strategy for implementation. CMS received OMB approval in May 2013.

This project will estimate probable fraud in the Home Health benefit to pilot test the measurement approach and calculate a service-specific estimate. This pilot is measuring “probable fraud” rather than “fraud” because “fraud” is a legal determination that involves establishing intent – a determination that is made through the judicial system. A review panel of experienced health care analysts, clinicians, policy experts, and fraud investigators will review all collected data and determine if there is sufficient evidence to warrant a referral to law enforcement. After the completion of this pilot, CMS will assess the value of expanding the measurement to other areas of Medicare. CMS will begin collecting data on probable fraud and have an estimate of probable fraud within HHAs in 2015.

4. Recovery

Suspension

CMS in FY 2014 continued its use of the new Affordable Care Act authority to suspend payments to providers during an investigation of a credible allegation of fraud. CMS also has authority to suspend payment if reliable information of an overpayment exists. During FY 2014, there were 507 payment suspensions that were active at some point during the fiscal year. Of the 507 payment suspensions, 207 new payment suspensions were imposed during FY 2014. This means that 300 were approved prior to FY 2014, but still active at some point during FY 2014. Lastly, during FY 2014, we terminated 191 payment suspensions.

Field Offices

CMS has designated program integrity field offices located in or near the HEAT cities of Miami, Los Angeles, and Brooklyn that provide a CMS presence in high risk fraud areas of the country. All three field offices have staff that are designated CMS Strike Force Liaisons, who coordinate with law enforcement, facilitate data analysis, and expedite suspension requests. The field offices also work with CMS central office and the ZPICs to conduct data analysis to proactively identify targets and to coordinate efforts among various contractors and agencies to identify local issues and vulnerabilities with national or regional impact.

The field office staff performs outreach and education to partners in their areas, including law enforcement, Senior Medicare Patrol and state Medicaid agencies. The field offices train US Attorneys, HHS-OIG and FBI agents, analysts and forensic accountants on Medicare policy and coding clarification, as well as provide data and billing analysis for specific cases. These staff also provides significant support during the prosecution of health care fraud cases through testimony, depositions and victim impact statements.

The field offices develop solutions to the most challenging program integrity issues in their region. In Miami, for example, the field office has boots on the ground working to root out fraud in home health by performing provider and beneficiary interviews. This has resulted in 105

revocations from the Miami Field office for FY 2014. The Los Angeles staff is working with county Emergency Medical Service licensing authorities, CMS contractors and local law enforcement to address emerging schemes in ambulance providers.

Enrollment Special Study

This is a project designed to utilize and expand the existing programmatic infrastructures to take administrative actions under existing CMS authorities by conducting site verifications of potentially high risk providers and suppliers. The information obtained during site verifications is used to determine if provider enrollment requirements are met and to calculate a fraud level indicator.

Since inception in July 2009, this project has produced significant results; including an increased number of revocations, deactivations, and prepay edit savings. The project has also provided valuable information which CMS has used to identify and implement programmatic changes that have proven successful to deter and prevent Medicare fraud.

As of June 30, 2014, the Medicare Administrative Contractor covering Florida, (First Coast Service Operations) had conducted 6,254 site verifications to verify providers' and suppliers' operational status, deactivated 16 practice locations, and revoked or denied 219 providers. CMS saved \$10,848,246 from prepayment medical record review

Administration for Community Living

The mission of the Senior Medicare Patrol (SMP) program is to empower and assist Medicare beneficiaries, their families, and caregivers to prevent, detect, and report health care fraud, errors, and abuse through outreach, counseling, and education. In FY 2014, the Administration for Community Living (ACL) was allocated \$3.4 million in HCFAC funding by HHS to support infrastructure, technical assistance, and other SMP program support. In addition to this funding, ACL was allocated \$3.2 million for capacity-building activities designed to enhance the effectiveness of state-wide SMP programs. During FY 2010 and FY 2011, CMS had provided this capacity funding to ACL for the SMP projects. In FY 2012 and FY 2013 HCFAC funding was allocated directly to ACL. The base SMP project grant is funded from a separate Congressional appropriation.

SMP Project Activities and Outcomes

ACL funds 54 SMP statewide projects (each state, Guam, Puerto Rico, US Virgin Islands and D.C.) with funds authorized in the Older American Act and the HCFAC Wedge. In addition to the projects' base grants, funded from the Older American Act, the SMP program offers HCFAC funds to each grantee so that they can expand their program. Prior to FY 2013, the additional funding was based largely on the known fraud prevalence within each state. However, in FY 2013, the program moved to a formula-driven allocation taking into account the number of Medicare beneficiaries living in each state and the ruralness of the state. The new formula is intended to provide a more equitable allocation of funds and reflects the reality that the prevalence of fraud is much broader than a few selected states.

According to the most recent annual performance report from HHS-OIG's Deputy Inspector General for Evaluation and Inspections, issued June 2014, a total of 5,406 active volunteers served SMP projects during 2013. These volunteers performed an essential function of this program, contributing 105,235 hours and conducting over 148,000 one-on-one counseling sessions in efforts to educate beneficiaries about how to prevent and detect Medicare fraud within local communities.

Outreach to Medicare beneficiaries is a key element of the SMP program. During 2013, SMP projects held 10,545 community outreach education events reaching more than 1,048,000 people, and were responsible for over 181,143 media airings to increase beneficiary awareness about issues related to Medicare fraud. In addition, over 501,400 beneficiaries were educated through 14,924 group educational sessions conducted by SMP programs in local communities.

SMP projects nationwide received 114,625 inquiries for information or assistance in 2013 from or on behalf of beneficiaries. This included receipt of 1,674 complex issues, i.e., beneficiary complaints requiring further research, assistance, case development, and/or referral. SMP projects reported that 1,526 complex issues were resolved for beneficiaries during 2013, while 698 complex issues with an estimated dollar value of over \$976,400, were referred to law enforcement, CMS integrity contractors, state Medicaid Fraud Control Units, or other entities for further action. During this period, HHS-OIG documented that \$143,282 in health care expenditures were avoided and nearly \$9.1 million in Medicare, Medicaid and other savings resulted from actions taken by the SMP program.

Since the program's inception, the program has educated over 5.9 million beneficiaries in group or one-on-one counseling sessions and has reached more than 29 million people through community education outreach events. While SMPs make numerous referrals of potential fraud to investigators, it is still difficult to measure the outcome of these cases without a tracking mechanism. Therefore, we have no specific measure of these outcomes, though we anticipate that they would demonstrate an additional benefit of the SMP program's ability to detect and prevent fraud and abuse in the Medicare program. In addition, the impact of the SMP program's primary activities – education of beneficiaries to prevent health care fraud – is extremely difficult to quantify in dollars and cents. As HHS-OIG indicated in the June 2014 report:

We continue to emphasize that it is not always possible to track referrals to Medicare contractors or law enforcement from beneficiaries who have learned to detect fraud, waste, and abuse from the projects. Therefore, the projects may not be receiving full credit for savings attributable to their work. In addition, the projects are unable to track the substantial savings derived from a sentinel effect whereby fraud and errors are reduced by Medicare beneficiaries' scrutiny of their bills.

ACL recognizes the importance of measuring the value of the SMP program impact to the fullest degree possible. Toward that end, in 2012, ACL contracted for the first-ever SMP program evaluation that assessed the national design and implementation of the SMP program, the adequacy of current SMP performance measures, and sought to determine the most appropriate measures of SMP program value (benefits, results and impact). The contract concluded in December 2013 and ACL is reviewing the evaluation recommendations for implementation in

FY 2015. In addition, in FY 2013, the SMP program issued a three-year research grant designed to measure the value of prevention activities. As the SMP program is focused on education and prevention, the true value of the program comes from beneficiaries avoiding fraud in the first place. This grant is intended help the program identify a way to measure that effect.

Despite the factors that have limited ACL's ability to quantify the value of the SMP program in preventing, identifying, and reporting health care fraud, HHS-OIG has documented over \$121 million in savings attributable to the program as a result of beneficiary complaints since its inception in 1997.

SMP Infrastructure and Program Support

SMP Resource Center

In FY 2014, the SMP Resource Center's grant was up for competition and a new three-year grant was awarded. The SMP Resource Center, established October 1, 2003, provides technical assistance, support and training to the SMP projects, ensuring a fully consolidated national approach to reaching Medicare and Medicaid beneficiaries. The goal of the Center is to provide professional expertise and technical support, serve as an accessible and responsive central source of information, and maximize the effectiveness of the SMP projects in health care integrity outreach and education. The Center has been instrumental in supporting ACL efforts to forge national visibility for the SMP program.

SMP Data System

The SMP program issued a contract in FY 2014 for the development of a new data system designed to support the evolving needs of the SMP program. The previous system, SMART FACTS, has been in operation for seven years and is at the end of its functionality. The new system will be operational in late FY 2015 and is expected to last at least 10 years.

Integration Project Grants

The goal of the SMP program is to provide education to all Medicare beneficiaries. However, there are specific populations that are historically hard to reach. Three of these populations-- Medicare beneficiaries under age 65; Lesbian, Gay, Bisexual and Transgender (LGBT) Medicare beneficiaries; and American Indian/Alaska Native (AI/AN) Medicare beneficiaries--were specifically identified as target populations. In FY 2013, ACL awarded five grants to organizations that have initiated seventeen-month projects seeking to increase awareness, empowerment, and actions to prevent health care fraud amongst these generally underserved populations. The goal of these grants is to develop new, efficient, and sustainable approaches for ensuring high-quality and culturally competent service delivery and help educate consumers to prevent health care fraud. This work continued in FY 2014.

Prevention Research Grant

As mentioned above in FY 2013, the SMP program issued a three-year research grant to identify a way to measure the overall impact of the SMP program. Specifically, the grantee will develop and test an evaluation method to determine how to best measure the effects of the SMP program's community education techniques on health care fraud prevention. This work continued in FY 2014.

Office of the General Counsel

In FY 2014, the Office of the General Counsel (OGC) was allocated approximately \$13 million in HCFAC funding by HHS to supplement OGC's efforts to support program integrity activities. Many of OGC's efforts in FY 2014 were focused heavily on program integrity review, in which OGC reviews CMS' programs and HCFAC activities in order to strengthen them against potential fraud, waste, and abuse. OGC also continued its active litigation role in order to assist in the recovery of program funds. During FY 2014, OGC was involved in a wide range of HCFAC efforts that resulted in Government recoveries of over \$2.5 billion in judgments, settlements, or other types of recoveries, savings, or receivables as described elsewhere in this report.

The Affordable Care Act

The ACA significantly amended existing anti-fraud statutes. These provisions established fundamental expectations for compliance, disclosure, transparency, and quality of care, and are matched by corresponding enforcement provisions. Some specific provisions of the ACA that particularly support HCFAC priorities include amending Medicare and Medicaid provider/supplier enrollment requirements, overpayment provisions to specifically invoke the FCA, strengthening the anti-kickback statute, and creating a statutory disclosure protocol for violations of the physician self-referral prohibition known as the "Stark law." During FY 2014, as new ACA programs continued to be implemented, OGC spent significant time and resources working with the relevant CMS client components to ensure that program integrity issues were reviewed and resolved, and assisted the client in addressing program integrity and compliance problems as they occurred.

HEAT

During FY 2014, OGC was involved in HEAT initiatives and worked closely with other HEAT members to combat fraud, waste, and abuse in the Medicare and Medicaid programs by providing advice on the myriad legal issues presented as the government works to initiate innovative anti-fraud programs in various hotspots throughout the country. OGC continued to assist DOJ in pursuing both criminal and civil cases involving individuals and entities seeking to defraud the Medicare and Medicaid programs and to defend any Federal court challenges that are brought as a result of HEAT initiatives. OGC's involvement in HEAT also included advising CMS on provider and supplier revocations, payment suspensions, recoupments, and defending the administrative appeals that resulted.

FCA and Qui Tam Actions

OGC supported DOJ in assessing qui tam actions filed under the FCA by interpreting complex Medicare and Medicaid rules and policies to assist DOJ in discerning which allegations were program violations and should be pursued, and to help DOJ focus government resources on those matters which were most likely to result in a recovery of money for the government. When DOJ filed or intervened in a FCA matter, OGC provided litigation support, including interviewing and preparing witnesses and responding to requests for documents and information. OGC also expended considerable resources in responding to requests for information and witness testimony in declined qui tams that were litigated by relators. In FY 2014, OGC participated in FCA and related matters that recovered over \$2.2 billion for the government. The types of FCA cases that

OGC worked collaboratively with DOJ on included: drug pricing manipulation, illegal marketing activity by pharmaceutical manufacturers that resulted in Medicare and Medicaid paying for drugs for indications not covered, physician self-referral violations, and provider upcoding cases.

Provider/Supplier Suspensions and Enrollment Revocations or Denials

Suspensions play a critical role in protecting against the abuse of program funds. OGC advised CMS on whether to suspend payments to Medicare providers and suppliers and defended the suspensions when challenged through the appeal process. In FY 2014, OGC attorneys were involved in a myriad of suspension and recoupment actions, which involved fraudulent billings by many different segments of the health care industry, including DME suppliers, ambulance companies, physicians, infusion clinics, therapists, home health agencies, and diagnostic testing facilities. OGC also represented CMS when a provider or supplier appealed a denial of enrollment or revocation. In FY 2014, OGC represented CMS in appeals before the Departmental Appeals Board (DAB) and often resolved these cases without formal hearings. OGC also continued to advise CMS on the interpretation of enrollment regulations and reviewed proposed enrollment rules and manual changes.

Medicare Prescription Drug Program (Part D) & Medicare Advantage (Part C) Compliance

During FY 2014, OGC continued to provide extensive advice to CMS on a variety of Part D and MA-related contract compliance issues, including identifying enforcement options against sponsors that are noncompliant or violate program rules, such as the Marketing Guidelines. OGC reviewed compliance-related correspondence that CMS issued to Part D sponsors and MA plans in the form of warning letters, corrective action plan letters, intermediate sanctions, CMP notices, and non-renewal or termination notices.

Civil Monetary Penalties

CMS has the responsibility for administering numerous CMP provisions enacted by Congress to combat fraud, waste, and abuse by enforcing program compliance and payment integrity. In FY 2014, OGC provided legal advice to CMS regarding the development and imposition of CMPs and defended CMS in many administrative appeals and judicial litigation resulting from these cases.

Petitions for Remission

OGC collaborated with Federal law enforcement, including the FBI, the USAOs, the Secret Service, U.S. Postal Service, and the U.S. Marshal's Service in filing petitions for remission directed to recover assets subject either to administrative forfeiture by Federal law enforcement or civil judicial forfeiture by DOJ. Each petition set forth the background of the fraudulent scheme, the history of Medicare's payments, and how the fraudulently induced payments could be traced to the seized assets. During FY 2014, OGC petitioned these agencies to recover funds in both criminal and civil litigation matters in which Medicare was a victim of fraud.

Regulatory Review and Programmatic Advice

In FY 2014, OGC advised CMS on a vast variety of regulatory and program issues, all to assist CMS in strengthening its programs and activities against fraud and to prevent the wrongful disbursement of program funds in the first instance. Some highlights of OGC efforts include:

providing counsel to the CMS “Innovation Center” regarding new payment and delivery models to improve the quality of care and reduce costs to the Medicare and Medicaid programs, working with CMS to implement the agency’s second notice related to provider and supplier enrollment moratoria, and providing counsel on a proposed rule updating survey procedures and alternative sanctions available for HHAs that are not meeting program participation requirements. Further, OGC worked with several CMS components on a final rule issued in May 2014 that implemented certain ACA program integrity provisions. The final rule requires physicians and practitioners who write prescriptions for covered Part D drugs to be enrolled in Medicare, established new authority to revoke a prescriber’s Medicare enrollment in certain situations, and implemented ACA requirements regarding reporting and returning of overpayments by Part C and D plans. In addition, OGC routinely works with CMS to review legislative proposals regarding program integrity matters.

Medicaid Integrity

Continuing recent trends, OGC saw continued increasing involvement in FY 2014 in Medicaid integrity issues as CMS devoted more resources to financial reviews and oversight and as states continued to present innovative proposals to reconfigure their Medicaid programs. For example, OGC assisted CMS with an advocacy group’s administrative complaint filed against Ohio’s Medicaid fair hearing appeals process. OGC is also opposing the Detroit-Wayne Mental Health Authority’s challenge before the Departmental Appeals Board of the Division of Cost Allocation’s denial of the Authority’s request to use \$4.8 million of unspent Medicaid funds to reduce its pension obligations. OGC also assisted CMS with the Indiana Medicaid Program’s pilot project to recover Medicare overpayments through the offset of the Federal Financial Participation (FFP) portion of Medicaid payments. To date, the pilot project has recovered over \$900,000. OGC anticipates providing similar support to CMS with a recently launched initiative with the State of Ohio Medicaid Program.

Physician Self-Referral

OGC provided valuable assistance to CMS and DOJ in navigating the complexities of the Stark physician self-referral law. This consultation helps to build stronger cases and focus investigatory efforts, leading to successful results for the government. In FY 2014, OGC provided extensive counsel to CMS in its ongoing implementation of the Medicare Physician Self-Referral Disclosure Protocol (SRDP)—created under the ACA to enable Medicare providers to self-disclose technical violations of the Stark law’s physician self-referral prohibition. OGC advised CMS regarding numerous matters disclosed under this protocol, now numbering over 300.

Medicare Secondary Payer (MSP) Workload

OGC’s efforts to recover conditional payments by Medicare that are the primary responsibility of other payers directly supports the HCFAC statutory goal of facilitating the enforcement of all applicable legal remedies for program fraud and abuse. During FY 2014, OGC has been successful in establishing the right to recover over \$6.5 million for Medicare under the MSP program. Further, statutory changes implementing mandatory insurance reporting requirements to the MSP law have strengthened and expanded OGC’s efforts in this area – to the benefit of the Medicare Trust Funds – including the authority for CMS to impose substantial CMPs for failure to report.

Bankruptcy Litigation

OGC protects Medicare funds from waste in bankruptcy cases by asserting CMS recoupment rights to collect overpayments, arguing to continue suspension or termination actions against debtors, seeking adequate assurances from the bankruptcy court that CMS interests in the debtor's estate will be protected, arguing for the assumption of the Medicare provider agreement as an executory contract, and petitioning for administrative costs where appropriate. In FY 2014, OGC asserted CMS' interests in numerous bankruptcy and receivership actions involving physicians, hospitals, independent diagnostic test facilities, DME suppliers, nursing homes, and nursing home chains, collecting or establishing the right to collect over \$900,000 in recoveries involving bankrupt providers.

Denial of Claims and Payments

CMS and its contractors engaged in various activities and initiatives to detect and prevent abusive and fraudulent billing practices. These measures included provider and beneficiary education, use of claim sampling techniques, and a more rigorous scrutiny of claims with increased medical review. In FY 2014, OGC played a major role in advising CMS regarding the development and implementation of these types of program integrity measures and defended CMS in litigation brought by providers and suppliers who challenged these efforts. OGC continued to aggressively defend CMS and its contractors in cases seeking damages for the alleged wrongful denial of claims, for being placed on payment suspension, and for not being granted extended repayment plans.

In summary, OGC's work in support of CMS advances the specific goals of the HCFAC program, including program integrity, fraud prevention, and fraud response. Most CMS operations have a fraud/abuse component, and OGC's work supporting all CMS substantive program areas directly supports the HCFAC program's goals of fraud and abuse prevention in those operational program areas.

Food and Drug Administration Pharmaceutical Fraud Program

In FY 2014, \$3.4 million in HCFAC funding was made available for the FDA Pharmaceutical Fraud Program (PFP). The PFP was instituted to enhance the health care fraud-related activities of FDA's Office of Criminal Investigations (OCI) and the Office of the General Counsel (OGC) Food and Drug Division. OCI, with the support of OGC, investigates criminal violations of the Federal Food, Drug, and Cosmetic Act (FFDCA), the Prescription Drug Marketing Act, the Federal Anti-Tampering Act, and related Federal statutes.

The PFP is designed to detect, prosecute, and prevent pharmaceutical, biologic, and medical device fraud. The PFP gathers information from sources inside and outside FDA and focuses on fraudulent marketing schemes, application fraud, clinical trial fraud, and flagrant manufacturing-related violations concerning biologics, drugs, and medical devices. The goal of the program is the early detection and prosecution of such fraudulent conduct and furthers FDA's public health mission by helping to reduce health care costs, in most cases before they are incurred, and deter future violators. By initiating investigations of pharmaceutical fraud schemes earlier in their lifecycle, FDA is able to preclude potential public harm by barring medical products, which

have not followed the legal FDA approval processes and do not meet FDA standards, from making it to market while saving valuable healthcare dollars from being spent on these bogus products.

As described below, the PFP has identified multiple alleged medical product fraud schemes through various avenues.

Since the inception of the PFP, OCI has opened a total of eighty-nine criminal investigations. In FY 2014, FDA's fourth full fiscal year of HCFAC Program activity, OCI, through its PFP, opened twenty-four criminal investigations, described below:

- Two investigations involving misbranding allegations by drug manufacturers, including minimization of risk and marketing for unapproved uses. These investigations involve marketing of the drugs for conditions not indicated in the approved labeling and for deceptive marketing practices regarding the safety of the products.
- Four investigations involving allegations of misbranding by medical device manufacturers for selling or distributing devices for conditions which are not FDA cleared and for making misleading representations about the device benefits and efficacy.
- Six investigations involving allegations of flagrant manufacturing practices concerning both drugs and devices causing those products to be misbranded or adulterated and resulting in a safety risk to the public.
- Twelve investigations involving allegations of clinical trial or application fraud. These investigations consist in part of individuals suspected of improperly commencing and conducting clinical trials, falsifying clinical trial data, forging signatures of clinical investigators, and enrolling ineligible or non-existent subjects in clinical trials, as well as falsifying approval or clearance applications made to the FDA.

In regards to judicial action, the types of criminal investigations conducted through the PFP tend to be complex in nature requiring extensive document review and coordination with the affected FDA Center. It is not unusual for these complex fraud investigations to last five years or more from initiation to conclusion. Nevertheless, in January and February 2014, an application fraud investigation, opened in FY 2011, obtained three guilty pleas for submitting a report to the FDA which was materially false or misleading during the device approval process. Two individuals and the corporation were sentenced to a total of 84 months of probation and were ordered to pay fines and restitution totaling approximately \$343,000. Additionally, in August 2014, a clinical trial coordinator who falsified patient data, pled guilty to making false statements in a matter within the jurisdiction of the FDA and is awaiting sentencing.

Furthermore, FDA believes that various investigations already initiated under the PFP show promise of future judicial action that may include criminal prosecution and monetary recoveries. These cases include several investigations of large international drug

manufacturers whose active pharmaceutical ingredients are destined for the U.S. market for serious and pervasive manufacturing violations, as well as several investigations of clinical trial organizations, study coordinators, principal investigators and sponsors who have allegedly fabricated study subjects, omitted exclusion and inclusion criteria and caused false data to be submitted to the FDA which represented the investigational products were safe and effective when, in fact, they are not.

In addition to these investigative activities, FDA conducted a three day training session in early May 2014 for criminal investigators and supervisors covering PFP related topics. The instruction consisted of legal training provided by OGC on the FDCA in areas relevant to PFP cases, investigative scenario training on relevant PFP investigations and case presentations on successful prosecutions involving misbranding and other fraud schemes encompassing both drugs and medical devices. The training also provided background on FDA's participation in the HCFAC Program and resources available to assist in investigations being conducted under the PFP. Due to this training, FDA has seen a measurable increase in HCFAC Program awareness, interest, and level of skill in conducting the investigations.

DEPARTMENT OF JUSTICE

United States Attorneys

In FY 2014, the United States Attorneys' Offices (USAOs) were allocated approximately \$40.7 million in HCFAC funding to support civil and criminal health care fraud and abuse litigation, as exemplified in the Program Accomplishments section. The USAOs dedicated substantial district resources to combating health care fraud and abuse in 2014, and HCFAC allocations have supplemented those resources by providing funding for attorneys, paralegals, auditors and investigators, as well as funds for litigation of resource-intensive health care fraud cases.

The 93 United States Attorneys and their assistants, or AUSAs, are the nation's principal prosecutors of Federal crimes, including health care fraud. Each district has a designated Criminal Health Care Fraud Coordinator and a Civil Health Care Fraud Coordinator. Civil and criminal health care fraud referrals are often made to USAOs through the law enforcement network described herein, and these cases are usually handled primarily by the USAOs, although the civil referrals are sometimes handled jointly with the Civil Division's Commercial Litigation Branch (Fraud Section). The other principal source of referrals of civil cases for USAOs is through the filing of qui tam (or whistleblower) complaints. These cases are often handled jointly with trial attorneys in the Fraud Section. USAOs also handle most criminal and civil appeals at the Federal appellate level.

USAOs play a major role in health care fraud enforcement by bringing criminal and affirmative civil cases to recover funds wrongfully taken from the Medicare Trust Funds and other taxpayer-funded health care systems as a result of fraud, waste, and abuse. Civil and criminal AUSAs litigate a wide variety of health care fraud matters, including false billings by physicians and other providers of medical services, overcharges by hospitals, Medicaid fraud, and kickbacks to induce referrals of Medicare or Medicaid patients, fraud by pharmaceutical and medical device companies, home health and hospice fraud, and failure of care allegations against nursing home owners. Working closely with their partners in the Civil Division, several civil health care fraud AUSAs have focused their efforts on pharmaceutical fraud, resulting in significant recoveries. Most notably, health care giant Johnson & Johnson agreed to pay \$2.2 billion to resolve criminal and civil liability arising from allegations relating to the prescription drugs Risperdal, Invega and Natrecor, including promotion for uses not approved as safe and effective by the Food and Drug Administration (FDA) and payment of kickbacks to physicians and to the nation's largest long-term care pharmacy provider.

Other major pharmaceutical cases included: Endo Health Solutions Inc., which agreed to pay to pay \$192.7 million to resolve criminal and civil liability arising from Endo's marketing of the prescription drug Lidoderm for uses not approved as safe and effective by the FDA; and Teva Pharmaceuticals USA Inc., which agreed to pay the government and the State of Illinois \$27.6 million for allegedly violating the FCA by making payments to induce prescriptions of an anti-psychotic drug for Medicare and Medicaid beneficiaries. Most of the major civil settlements

were part of a global resolution, which also addressed the criminal liabilities, resulting in criminal pleas, as well as significant fines and forfeitures. The criminal portion of these investigations and resolutions was handled by criminal health care fraud AUSAs, often working with their counterparts at the Consumer Protection Branch of the Civil Division. These global settlements resolved allegations including, reporting of false and inflated drug prices, manufacturing and distributing adulterated drugs, off-label marketing and kick-backs. These cases are detailed earlier in this report.

The USAOs partner with the Criminal Division in the Medicare Fraud Strike Forces currently operating in nine areas across the country. Each USAO has dedicated several AUSAs and support personnel to work with Criminal Division attorneys in this important initiative. The Strike Forces use data analysis to identify high-billing levels in health care hot spots so that emerging or migrating schemes can be targeted. The significant successes of the Strike Forces are detailed earlier in this report.

In addition to the positions funded by HCFAC, the Executive Office for United States Attorneys' Office of Legal Education (OLE) uses HCFAC funds to train AUSAs and other DOJ attorneys, as well as paralegals, investigators, and auditors in the investigation and prosecution of health care fraud. In 2014, OLE offered a Current Trends in Health Care Fraud Seminar, which was attended by over 70 AUSAs and DOJ trial attorneys. Many USAO attorneys, investigators, auditors, and paralegals serve as faculty at these OLE trainings, and also participate in other Federal, state, and private health care fraud seminars.

Criminal Prosecutions¹²

In FY 2014, the USAOs received 924 new criminal matters. During FY 2014, the USAOs filed criminal charges in 496 cases involving 805 defendants, and obtained 734 federal health care fraud related convictions.

Civil Matters and Cases¹³

In FY 2014, the USAOs had opened 782 new civil health care fraud investigations. At the end of FY 2014, the USAOs had 957 civil health care fraud investigations pending.

Civil Division

In FY 2014, the Civil Division received approximately \$27.1 million in FY 2014 HCFAC funding to support the health care fraud activities of the Commercial Litigation Branch's Fraud Section and the Consumer Protection Branch. This amount also included funding to support the Department of Justice's Elder Justice Initiative.

¹² FY 2014 numbers are actual data through the end of September 2014. This data includes records classified either with the primary or tertiary 03G – Health Care Fraud program code.

¹³ FY 2014 numbers are actual data through the end of September 2014. This data includes those records classified under with the FRHC – Health Care Fraud civil code.

The Commercial Litigation Branch's Fraud Section

The Civil Division's Commercial Litigation Branch (Fraud Section) investigates complex health care fraud allegations and files suit under the FCA to recover money on behalf of defrauded federal health care programs including Medicare, Medicaid, TRICARE, and the FEHBP. The Fraud Section works closely with the Consumer Protection Branch, United States Attorneys' Offices, HHS-OIG, state Medicaid Fraud Control Units and other law enforcement agencies. As a result of these efforts, the Fraud Section has obtained settlements and judgments in health care cases of over \$1 billion almost every year since 2000 and over \$2.3 billion in FY 2014 alone.

The Fraud Section investigates and resolves matters against a wide array of health care providers and suppliers. Matters involving pharmaceutical and device manufacturers have historically been some of the most complex and resource intensive cases handled by the Fraud Section. These matters commonly involve nationwide conduct, raise legally and factually complicated issues, and demand significant resources to investigate, resolve, and litigate, if necessary. Many of these cases—including the Johnson & Johnson, Shire, and Endo matters discussed above—involved allegations that the pharmaceutical manufacturer improperly promoted its drug for uses not approved by the FDA and not covered by federal health care programs. Other cases, like the CareFusion and Gensyme matters, involved allegations relating to the manufacture and distribution of medical devices that were misbranded or not approved by the FDA. Lastly, many pharmaceutical and medical device fraud cases involve allegations that the drug or device manufacturer paid kickbacks to physicians to prescribe its products. These cases are significant not only because of the significant dollars involved, but also because they protect Medicare and Medicaid beneficiaries by preserving the integrity of the FDA's approval process as well as the doctor-patient relationship.

In addition to pharmaceutical fraud, the Fraud Section also investigated and resolved matters involving hospitals and physicians. For example, the Fraud Section resolved allegations that hospitals overbilled Medicare by treating patients on an inpatient basis when they should have been treated as observation patients or on an outpatient basis (e.g., the Community Health Systems, Inc. and Carondelet Health Network matters discussed above) and allegations that hospitals performed medically unnecessary coronary stenting procedures (e.g., the King's Daughter Medical Center and St. Joseph Medical Center matters discussed above). Likewise, on the eve of trial, the Fraud Section successfully resolved litigation against Halifax Hospital involving allegations that its contracts with employed medical oncologists and neurosurgeons violated the Stark Law. As a result of its investigation, the government recovered \$85 million.

Because the Fraud Section receives every FCA complaint filed across the country by whistleblowers (otherwise known as "relators"), it has a unique vantage point over health care fraud trends and developments nationwide and therefore regularly handles some of the most complex matters and takes the lead on coordinating national investigations with its law enforcement partners. Likewise, given the diversity of health care fraud cases pursued by the Fraud Section, it frequently provides training and guidance to AUSAs and agents on the FCA and health care fraud issues. The Section works closely with HHS-OIG, Office of General Counsel, in all settlements of health care fraud allegations in order to ensure that the administrative

remedies possessed by HHS are appropriately considered and to enable the negotiation of compliance terms that diminish the risk that the offending conduct will be repeated. The Section also collaborates with and counsels CMS and HHS-OIG on interagency initiatives and proposed rules and regulations.

The Elder Justice Initiative, which is housed in the Civil Division, coordinates and supports law enforcement efforts to combat elder abuse, neglect, and financial exploitation. The Initiative supports law enforcement efforts by maintaining an information bank of Elder Justice related materials (including briefs, opinions, indictments, plea agreements, subpoena templates); funding medical reviewers, auditors, and other consultants to assist DOJ attorneys and AUSAs in their nursing home and/or long term care facility cases; hosting quarterly teleconferences with DOJ attorneys and AUSAs across the country to discuss issues or developments in connection with our nursing home and failure of care cases; and coordinating nationwide investigations of skilled nursing facilities. In addition to supporting law enforcement efforts, the Initiative continues to fund research projects awarded by the Office of Justice Programs, National Institute of Justice, to study the abuse, neglect, and exploitation of elderly individuals and residents of residential care facilities. Elder Justice Initiative members represent the Justice Department on Interagency Working Groups such as the Elder Justice Coordinating Council's Working Group. In September 2014, the Civil Division launched the Elder Justice Website (www.justice.gov/elderjustice), a valuable resource for elder abuse victims and their families, state and local prosecutors, elder abuse researchers, as well as practitioners. The website will also serve as a forum for law enforcement and elder justice policy communities to share information and enhance public awareness about elder abuse.

The Consumer Protection Branch

The Consumer Protection Branch (CPB) investigates and prosecutes manufacturers and individuals who are illegally promoting and distributing unapproved, misbranded, and adulterated drugs and devices in violation of the Food, Drug, and Cosmetic Act (FDCA). CPB works closely with the Commercial Litigation Branch's Fraud Section, the USAOs, and the FDA on a wide variety of health care fraud matters. Because of the complex nature of these investigations, they demand significant resources. They often require in-depth analyses of manufacturers' clinical studies, manufacturing practices, or commercial activities. In recent years, CPB has prosecuted dozens of companies and individuals for FDCA and related violations. These prosecutions have resulted in significant jail terms and fines, penalties, and forfeitures; since 2009, these fines, penalties, and forfeitures have totaled more than \$6.4 billion.

In the area of pharmaceutical and medical device fraud, CPB has been actively involved in several significant settlements in FY 2014. In the Johnson & Johnson (J&J) matter, CPB, in partnership with the USAO, prosecuted J&J subsidiary Janssen for its misbranding of the antipsychotic drug Risperdal. Although Risperdal was approved only to treat schizophrenia, Janssen's sales representatives promoted Risperdal to physicians and other prescribers who treated elderly dementia patients by urging the prescribers to use Risperdal to treat symptoms such as anxiety, agitation, depression, hostility and confusion. Members of Janssen's ElderCare sales force used company created written sales aids that emphasized symptoms and minimized any mention of the

FDA-approved use, treatment of schizophrenia. In a plea agreement resolving these charges, Janssen admitted that it promoted Risperdal to health care providers for treatment of psychotic symptoms and associated behavioral disturbances exhibited by elderly, non-schizophrenic dementia patients. Under the terms of the plea agreement, Janssen paid a total of \$400 million, including a criminal fine of \$334 million and forfeiture of \$66 million.

In addition to prosecuting major pharmaceutical and medical device companies and responsible individuals for health care offenses, CPB prosecutes dangerous schemes involving the online sale of pharmaceuticals. For example, in FY 2014, CPB brought charges against fifteen individuals in connection with a global Internet pharmacy organization which unlawfully sold prescription drugs over the Internet through a network of websites and affiliates. This pharmaceutical drug trafficking organization facilitated the illegal distribution of prescription drugs, including Soma (containing Carisoprodol), Ultram (containing Tramadol), and Fioricet (containing butalbital, acetaminophen and caffeine), and their generic equivalents, based on invalid prescriptions, to customers throughout the United States. To date, five individuals have pled guilty.

The Consumer Protection Branch also prosecutes individuals who are purveyors of unapproved drugs, which are sold to consumers as purported cures for diseases. For instance, CPB worked with the U.S. Attorney's Office in Houston, Texas, to prosecute two individuals who were sentenced to 60 months and 78 months in prison, respectively, for their roles in a conspiracy to introduce unapproved drugs into interstate commerce. The defendants advertised and promoted unapproved stem cell treatments to individuals who had serious illnesses, such as amyotrophic lateral sclerosis (Lou Gehrig's disease), multiple sclerosis, and Parkinson's disease – diseases for which there is no FDA-approved cure. During the conspiracy, one defendant falsely represented to victims that he was a physician licensed to practice medicine in Texas and that he had extensive experience in carrying out stem cell procedures. Victims were falsely told by the second defendant that the stem cell procedures were FDA approved and would effectively treat their diseases. Cases such as these are significant because of the public health and safety issues that they implicate.

Criminal Division

In FY 2014, the Criminal Division was allocated \$8.6 million in FY 2014 HCFAC funding to support criminal health care fraud litigation and interagency coordination, which is carried out primarily by the Fraud Section and, to a lesser extent, the Organized Crime and Gang Section.

The Fraud Section

The Fraud Section in the Criminal Division prosecutes health care fraud cases, initiates and coordinates complex health care fraud prosecutions, and supports the USAOs with legal and investigative guidance and training. Beginning in March 2007, the Fraud Section, working with the local USAOs, the FBI, HHS-OIG, and state and local law enforcement agencies, launched the Medicare Fraud Strike Force in Miami-Dade County, Florida. Since 2007, DOJ and HHS have expanded Strike Force operations to nine areas. In FY 2014, the Fraud Section continued to provide attorney staffing, litigation support, and leadership and management oversight for

numerous Strike Force prosecutions in each Strike Force area. A summary of the Fraud Section's key litigation accomplishments in FY 2014 follows:

- Filed 165 new health care fraud cases involving charges against 353 defendants who collectively billed the Medicare and Medicaid programs approximately \$830 million;
- Obtained 304 guilty pleas and litigated 38 jury trials, winning guilty verdicts against 41 defendants;¹⁴ and
- Secured prison sentences in health care fraud cases averaging more than 50 months.

Fraud Section attorneys staffed and coordinated the Division's health care fraud litigation through the existing nine Medicare Fraud Strike Force teams.

Fraud Section attorneys coordinated a major multi-district Strike Force initiative during the fiscal year and handled many of the investigations and indictments that were filed in this operation. On May 13, 2014, Fraud Section and USAO Strike Force prosecutors in nine cities executed a nationwide operation that resulted in charges against 90 individuals, including doctors, nurses, and other medical professionals, for their alleged participation in Medicare fraud schemes involving approximately \$260 million in false billings.

In addition to Medicare Fraud Strike Force cases, the Fraud Section handles other complex corporate criminal health care fraud matters. Often, such cases are handled with AUSAs from USAOs or coordinated with parallel proceedings by DOJ Civil Division attorneys. Below are some representative cases:

- On October 23, 2013, the former CEO and co-owner of Orbit Medical, Inc. was indicted as part of a \$45 million scheme involving the falsification of medical records to support fraudulent claims for power wheelchairs. Orbit has been a major supplier of DME to Medicare. The defendant directed Orbit sales representatives in falsifying patient records to make it appear that particular Medicare beneficiaries qualified for power wheelchairs under Medicare's regulations when in fact, they did not. Prior to defendant's indictment, three Orbit sales representatives had also pleaded guilty to charges of one count of health care fraud conspiracy related to their roles in the scheme at Orbit.
- In August 2014, a patient referral source for a major hospital chain pleaded guilty to conspiracy to pay and receive health care bribes and kickbacks. Specifically, from approximately 2000 through 2012, the defendant received over \$1,000,000 in bribes and kickbacks from the hospitals in exchange for referring Medicaid patients. The hospitals submitted over \$400,000,000 in false and fraudulent claims to government health care programs.
- In August 2014, the Chief Executive Officer of a hospital owned and operated by a major hospital chain pled guilty to conspiracy to pay health care bribes and kickbacks in

¹⁴ Fraud Section attorneys were responsible for many of the cases summarized in the Medicare Fraud Strike Force section of this report.

exchange for Medicaid patient referrals. The hospital submitted hundreds of thousands of dollars in false and fraudulent claims to government health care programs.

In addition to health care fraud litigation, the Fraud Section also provided legal guidance to FBI and HHS-OIG agents, health program agency staff, AUSAs, and other Criminal Division attorneys on criminal, civil, and administrative tools to combat health care fraud. Throughout FY 2014, Fraud Section prosecutors met with federal prosecutors and agents across the United States to provide training, investigative leads based on data analysis, and related support. The Fraud Section also provided support in the following areas, among others: provided advice and written materials on issues including patient medical record confidentiality and disclosure; coordinated referrals of possible criminal HIPAA privacy violations from the HHS Office for Civil Rights; monitored and coordinated DOJ responses to legislative proposals, major regulatory initiatives, and enforcement policy matters; reviewed and commented on health care provider requests to the HHS-OIG for advisory opinions and consulted with the HHS-OIG on draft advisory opinions; coordinated with CMS concerning fraud detection of Medicare contractors, referrals to law enforcement for investigation, and case development; and prepared and distributed to all USAOs and FBI field offices periodic summaries of recent and significant health care fraud cases. The Fraud Section also held a National Health Care Fraud Training Conference in September 2014 that was attended by 260 criminal and civil prosecutors (representing 50 U.S. Attorneys' Offices) and law enforcement personnel.

The Organized Crime and Gang Section (OCGS)

The Criminal Division's Organized Crime and Gang Section (OCGS) supports and participates in investigations and prosecutions of fraud and abuse targeting the 2.5 million private sector health plans sponsored by employers and/or unions, as well as investigations and prosecutions of health care frauds perpetrated by domestic and international organized crime groups. OCGS also works to improve strategic coordination in the identification and prosecution of domestic and international organized crime groups engaged in sophisticated frauds posing a threat to the health care industry.

Despite continuing budgetary austerity in FY 2014, four OCGS attorneys were assigned to health care fraud prosecutions. Two OCGS attorneys worked with the Organized Crime Strike Force in the Philadelphia United States Attorney's Office on prosecutions of Medicare fraud in the operation of a hospice and ambulance companies. A third OCGS attorney worked with the United States Attorney's Office in the District of Columbia on an investigation and prosecution of health care fraud involving a private employee health plan. The fourth OCGS attorney handled the investigation and prosecution of an employer who created false documents to conceal the company's underpayment of required contributions for employee benefits in the District of Maryland.

In Philadelphia, one OCGS attorney worked on prosecutions involving multiple indictments which charged a total of eight defendants in connection with a scheme to defraud Medicare by submitting \$14.3 million in fraudulent medical claims for hospice services provided to patients who did not receive services or were ineligible for the benefits claimed. The scheme was

successful because nurses and other staff participated in the massive fraud that involved altering patient records to make patients appear eligible for hospice services when, in reality, they were not. To build up patient enrollment, the hospice co-owners paid health care professionals, including doctors, for referring patients even when those patients were not eligible or appropriate for hospice services. In October 2013, a co-owner of the hospice was convicted after a four-week jury trial on 35 counts of health care fraud, conspiracy to commit health care fraud and money laundering. He was sentenced in May 2014 to more than 14 years' imprisonment and ordered to make \$16.2 million in restitution. A doctor who served as the medical director of the hospice was sentenced in October 2013 to 51 months' imprisonment for receiving more than \$300,000 in illegal payments for regularly referring Medicare and Medicaid patients to the hospice. The conviction resulted in the doctor's mandatory exclusion from participation in any federal health care program and will likely result in the loss of his medical license. One hospice nurse was convicted following a jury trial in connection with a conspiracy to defraud Medicare by fabricating and falsifying documents in support of hospice care for patients who were not eligible for hospice care, or for a higher, more costly level of care than was actually provided to the patients. The scheme involved the submission of approximately \$9,328,000 in fraudulent claims to Medicare and creation of fraudulent nursing notes for approximately 150 patients indicating that services were being provided, when, in reality, they were not. She was sentenced in June 2014 to 15 months' imprisonment and more than \$250,000 in restitution. Three additional hospice nurses pleaded guilty to conspiracy to defraud Medicare. One was sentenced in May 2014 to probation and restitution of \$189,000. One additional hospice nurse and one doctor await trial.

A second OCGS attorney worked with an AUSA in Philadelphia on prosecutions involving schemes to defraud Medicare through the operation of ambulance companies that billed Medicare for unnecessary services. In May 2014, the operator of one ambulance company moved the court to vacate his sentence of 92 months' imprisonment and set aside his guilty plea to a scheme to defraud Medicare of approximately \$5.4 million by billing for ambulance services that were not medically necessary. The Government has filed an opposition and the matter remains under consideration at the close of the fiscal year.

The District of Columbia prosecution involved theft from a collectively bargained health care benefit plan by a union officer and benefit plan trustee. The defendant entered a guilty plea in June 2014 to embezzlement from a health plan funded by employers pursuant to collective bargaining agreements with the union. He admitted to embezzling more than \$85,000 from the health fund, which was established to pay for the health benefits of union member employees. In September 2014, he was sentenced to nine months in a community corrections facility and ordered to pay \$85,000 in restitution to the health plan and \$107,000 in restitution to the union. As a result of this conviction, he is prohibited from serving as a health care benefit plan trustee, fiduciary or consultant or as a union officer for thirteen years from the date of his sentencing.

The District of Maryland case involved the victimization of a union health care plan by an employer who underpaid contributions to the plan which were required by a collective bargaining agreement and concealed the underpayment in plan records and reports. In August 2014, the company owner pleaded guilty to making false statements in documents required by the Employee Retirement Income Security Act from January 2009 through December 2011.

In addition to conducting health care fraud investigations and prosecutions, OCGS attorneys routinely provide litigation support and advice to AUSAs and criminal investigative agencies in the investigation and prosecution of corruption and abuse of private employment-based group health plans covered by the Employee Retirement Income Security Act (ERISA). Such private sector employment-based group health plans are the leading source of health care coverage for individuals not covered by Medicare or Medicaid. OCGS attorneys also provide support to investigations of fraud schemes by corrupt entities that sell unlicensed health insurance products as well as fraud schemes by corrupt employers that cheat workers out of health benefits required by the prevailing wage laws and regulations.

OCGS attorneys regularly provide health care fraud and abuse training and legal guidance to AUSAs and to criminal investigators and agents of the Department of Labor's Employee Benefits Security Administration and Office of Inspector General. Such training and guidance covers prosecutions involving abuse of private sector employee health plans subject to ERISA and health plans sponsored by labor organizations as well as fraud and abuse committed in connection with the operation of multiple employer welfare arrangements. OCGS also drafts and reviews criminal legislative proposals affecting employee health benefit plans. In addition, OCGS provides legal guidance to prosecutors and required approvals in the use of the Racketeer Influenced and Corrupt Organizations (RICO) statute in prosecutions of Medicare and Medicaid frauds as well as private sector health care frauds.

Civil Rights Division

In FY 2014, the Civil Rights Division was allocated approximately \$6.8 million in FY 2014 HCFAC funding to support Civil Rights Division litigation activities related to health care fraud and abuse. The Civil Rights Division pursues relief affecting public, residential and non-residential health care facilities and service systems. The Division conducts investigations to eliminate abuse and grossly substandard care in public, Medicare and Medicaid funded long-term care facilities. Consistent with the Supreme Court's decision in *Olmstead v. L.C.*, 527 U.S. 581 (1999), the Division has also undertaken initiatives to eliminate the needless institutionalization of individuals who require health care supports and services.

The Division plays a critical role in the HCFAC Program. The Special Litigation Section of the Civil Rights Division is the sole DOJ component responsible for the Civil Rights of Institutionalized Persons Act, 42 U.S.C. § 1997 (CRIPA). CRIPA authorizes the investigation of conditions of confinement at state and local residential institutions (including facilities for persons with developmental disabilities or mental illness, and nursing homes) and initiation of civil action for injunctive relief to remedy a pattern or practice of violations of the Constitution or Federal statutory rights. The review of conditions in facilities for persons who have mental illness, facilities for persons with developmental disabilities, and nursing homes is an element of the program.

The Disability Rights Section of the Civil Rights Division has primary enforcement authority for the Americans with Disabilities Act (ADA). Title II of the ADA authorizes investigation of allegations of discrimination by public entities against individuals with disabilities, including

discrimination in the form of needless institutionalization of persons who require health care supports and services. See *Olmstead*, 527 U.S. 581. Title II also authorizes the initiation of civil action to remedy discrimination in violation of the ADA. In addition to violating the civil rights of individuals with disabilities, such unnecessary institutionalization often results in unnecessarily increased Medicaid costs inconsistent with the Medicaid requirements for home and community-based services. Both the Special Litigation Section and the Disability Rights Section have undertaken initiatives to combat the use of Medicaid funding for the unjustified institutionalization of persons with disabilities. In addition, the Educational Opportunities Section initiated HCFAC Program participation during this fiscal year to address the use of Medicaid funding for unnecessary institutionalization of youth with disabilities in segregated education placements in violation of the ADA.

The Special Litigation, Educational Opportunities, and Disability Rights Sections work collaboratively with the USAOs and with HHS.

Fiscal Year 2014 Accomplishments

Special Litigation Section staff conducted preliminary reviews of conditions and services involving more than one hundred health care facilities in five states during FY 2014. The task in preliminary inquiries is to determine whether there is sufficient information supporting allegations of unlawful conditions and needless institutionalization to warrant formal investigation under CRIPA and/or the ADA. The Section reviews information pertaining to areas such as abuse and neglect, medical and mental health care, use of restraints, fire and environmental safety, and provision of services in the most integrated setting appropriate to individual needs. Separately, in FY 2014, the Section opened or continued formal investigations, entered remedial agreements, or monitored existing remedial agreements encompassing more than one thousand health care facilities in sixteen states and the District of Columbia. The large number of health care facilities reflects the Section's expanded focus on whether States are ensuring that nursing homes and other institutional settings do not inappropriately admit persons who should be served in more integrated settings.

In FY 2014, the Section entered into a letter agreement with the State of Mississippi outlining immediate steps the State must take toward resolving the Division's findings that practices at twelve state facilities for persons with intellectual and developmental disabilities and/or mental illness violate the residents' statutory rights. Those facilities are: Boswell Regional Center, in Magee, Mississippi; Ellisville State School, in Ellisville, Mississippi; Hudspeth Regional Center, in Pearl, Mississippi; Southern Mississippi Regional Center, in Long Beach, Mississippi; Mississippi Adolescent Center, in Brookhaven, Mississippi; North Mississippi Regional Center, in Oxford, Mississippi; Mississippi State Hospital, in Whitfield, Mississippi; South Mississippi State Hospital, in Purvis, Mississippi; Central Mississippi Residential Center, in Newton, Mississippi; East Mississippi State Hospital, in Meridian, Mississippi; North Mississippi State Hospital, in Tupelo, Mississippi; and the Specialized Treatment Center, in Gulfport, Mississippi. Further, the Section, along with a coalition of private plaintiff organizations, entered into a comprehensive settlement agreement with the State of New Hampshire in *Amanda D. v. Hassan*, (D. N.H.). The Settlement Agreement will significantly expand and enhance mental health

services in integrated community settings over the next six years. The Agreement will enable a class of thousands of adults with serious mental illness to receive services in the community, which will foster their independence and enable them to participate more fully in community life. It will significantly reduce visits to hospital emergency rooms and will avoid unnecessary institutionalization at State mental health facilities, including New Hampshire Hospital (the State's only psychiatric hospital) and the Glencliff Home (a State-owned and -operated nursing facility for persons with mental illness).

The Section oversaw the implementation of an interim settlement agreement in *Steward v. Perry*, (W.D. Tex.), to resolve a suit against the State of Texas for its failure to provide adequate community-based services to persons with intellectual disabilities residing in as many as 1,200 nursing homes across the State. Negotiations continued throughout the fiscal year to resolve all issues pursuant to a comprehensive agreement.

Also in FY 2014, the Section opened an investigation into South Dakota's utilization of nursing facilities across the state to serve seniors and people with disabilities. The Section also opened an investigation into West Virginia's use of multiple congregate settings to serve children with mental health and other needs.

The Section also continued its collaboration with the Office of United States Attorney for the Eastern District of New York in the investigation of one facility for persons with mental illness, Kingsboro Psychiatric Center, in Brooklyn, New York, and continued its investigation of Utah State Hospital, in Provo, Utah, and Utah's community service system for children with mental health needs.

The Section monitored the implementation of remedial agreements encompassing twenty facilities, and community service options, for persons with intellectual and developmental disabilities: Beatrice State Developmental Center, in Beatrice, Nebraska; Clover Bottom Developmental Center in Nashville, Tennessee; Greene Valley Developmental Center in Greeneville, Tennessee; Lubbock State Supported Living Center, in Lubbock, Texas; Denton State Supported Living Center, in Denton, Texas; Abilene State Supported Living Center, in Abilene, Texas; Austin State Supported Living Center, in Austin, Texas; Brenham State Supported Living Center, in Brenham, Texas; Corpus Christi State Supported Living Center, in Corpus Christi, Texas; El Paso State Supported Living Center, in El Paso, Texas; Lufkin State Supported Living Center, in Lufkin, Texas; Mexia State Supported Living Center, in Mexia, Texas; Richmond State Supported Living Center, in Richmond, Texas; Rio Grande State Supported Living Center, in Harlingen, Texas; San Angelo State Supported Living Center, in Carlsbad, Texas; San Antonio State Supported Living Center, in San Antonio, Texas; Central Virginia Training Center, in Lynchburg, Virginia; Northern Virginia Training Center, in Fairfax, Virginia; Southeastern Virginia Training Center, in Chesapeake, Virginia; and Southwestern Virginia Training Center, in Hillsville, Virginia. These remedial agreements include the provision of adequate community supports and services. The Section successfully concluded its monitoring of the three remaining Georgia State hospitals that serve both persons with mental illness and persons with intellectual or developmental disabilities, pursuant to the terms of its settlement with the State. The Section continued enforcement of a separate settlement that

requires the State to develop community resources to serve people with mental illness, and persons with intellectual or developmental disabilities, who were formerly institutionalized or at risk of institutionalization in the State Hospital facilities.

The Section brought to a successful close two decades of litigation regarding the rights of formerly institutionalized individuals with intellectual disabilities in West Tennessee, in *United States v. Tennessee*, (W.D. Tenn.). After the State expanded home-and-community-based services, changed the emphasis of its day services to supported employment and took other steps to successfully implement an agreed-upon “Exit Plan,” the court granted the parties’ joint request to dismiss this case.

The Section continued monitoring the implementation of various court orders in *Evans v. Gray*, (D. D.C.) intended to ensure that former residents of the District of Columbia’s Forest Haven institution for persons with intellectual or developmental disabilities receive appropriate community-based services, to prevent needless hospitalization or institutionalization.

The Section also monitored the implementation of remedial agreements regarding six state-operated residential facilities for persons with mental illness: Kings County Hospital Center, in Brooklyn, New York; Delaware State Psychiatric Center, in New Castle, Delaware; Connecticut Valley Hospital, in Middletown, Connecticut; New Hampshire Hospital, in Concord, New Hampshire; Glencliff Home for the Elderly, in Benton, New Hampshire; and Oregon State Hospital, in Portland, Oregon. These remedial agreements include the provision of adequate supports and services to enable individuals to live successfully in the community.

The Section successfully concluded its monitoring of six residential facilities for persons with mental illness in Georgia, three of which, as noted above, also have served persons with intellectual or developmental disabilities. The Section continued enforcement of a separate settlement that requires the State to develop community resources to serve people with serious mental illness who are at risk of institutionalization in the State Hospital facilities.

Separately, the Section asked a federal court to dismiss a consent decree addressing conditions of confinement and the ADA at Saint Elizabeths Hospital in Washington, D.C., after the District of Columbia complied with the decree by significantly improving conditions at the facility and implementing processes to transition individuals to more integrated settings that met their needs. That case was dismissed in September 2014. In addition, the Section monitored a remedial agreement at one nursing facility: the Maple Lawn Nursing Home, in Palmyra, Missouri.

In FY 2014, the Disability Rights Section continued to monitor the implementation of its eight-year settlement agreement with the State of North Carolina resolving the Section’s *Olmstead* investigation of North Carolina’s mental health service system, which currently serves thousands of individuals with mental illness in large, costly institutional settings known as adult care homes. Under the agreement, North Carolina is providing opportunities to individuals with mental illness in adult care homes to transition to less costly, supported housing settings – integrated housing that promotes inclusion and independence and enables individuals with mental

illness to participate fully in community life. To date, more than 250 individuals have moved from institutions to community-based settings.

The Section continued to litigate *Lane v. Kitzhaber* (D. Or.), a class action in which it intervened. The case was brought on behalf of persons with intellectual and developmental disabilities alleging that Oregon is in violation of Title II of the ADA and *Olmstead* by unnecessarily segregating individuals with disabilities in sheltered workshops, and placing other individuals at risk of unnecessary segregation in sheltered workshops, when such individuals can and want to work in more integrated supported employment settings. The litigation is ongoing.

The Section also continued to litigate *United States v. Florida* (S.D. Fla. 2013), a case in which the United States alleges that the State of Florida administers its service system for children with significant medical needs in violation of the ADA and *Olmstead* by unnecessarily segregating them in nursing facilities, when they could, and want to, be served at home or in other community-based settings.

The Section also entered into the nation's first statewide settlement agreement, in *United States v. Rhode Island*, addressing the unnecessary segregation of individuals with disabilities in segregated institutional sheltered workshops and facility-based day programs. Under the agreement, the State will provide community-based supported employment placements to roughly 2,000 individuals with intellectual and developmental disabilities, including at least 700 people currently in sheltered workshops, at least 950 people in facility-based day programs, and approximately 300-350 students leaving high school. The Section continues to monitor its previously entered, interim settlement agreement with the State of Rhode Island and the City of Providence.

The Section also monitored its settlement agreement with the State of New York and private plaintiffs regarding New York's mental health service system, in *United States v. New York* (E.D.N.Y. 2013). The agreement remedies discrimination by the State in the administration of its mental health service system and ensures that individuals with mental illness who reside in 23 large adult homes in New York City receive services in the most integrated setting appropriate to their needs consistent with the ADA and *Olmstead*. Under the agreement, such individuals will have the opportunity to live and receive services in the community such that they are able to live, work, and participate fully in community life. The Section also continued to monitor proceedings relating to the placement of children with disabilities at a restrictive facility that employs aversive treatment as a form of therapy.

In FY 2014, the Educational Opportunities Section (EOS), began its participation in the HCFAC Program and extended its investigation of the Georgia Network of Educational and Therapeutic Services (GNETS) program, which provides educational services for approximately 5000 students with emotional and behavioral disabilities. GNETS is funded and operated by the State of Georgia and provides educational services to most of the students in the program in segregated GNETS Centers that exist throughout the State of Georgia.

EOS has also begun to evaluate complaints from families of students in segregated educational facilities, including alternative schools, residential schools for students with disabilities, and residential treatment facilities. In August, the Section was co-counsel on a Statement of Interest in *S.S. v. City of Springfield, MA* (D. Ma), challenging placement of students with disabilities in alternative schools that exclusively educate students with disabilities who are often placed there after they exhibit challenging behaviors.

In addition to the *City of Springfield* matter, the Division filed four statements of interest or *amicus* briefs in litigation raising issues of needless segregation in Pennsylvania, Mississippi, and the U.S. Court of Appeals for the Third and Eleventh Circuits. These briefs have addressed issues relating to the unnecessary institutionalization of individuals in state-run and private, state-funded institutions.

APPENDIX

Federal Bureau of Investigation

In FY 2014, the FBI was allocated \$127.3 million in funding from HIPAA to support the facilitation, coordination and accomplishment of the goals of the HCFAC Program. This yearly appropriation was used to support 797 positions (476 Agent, 321 Support).

In FY 2014, the FBI initiated 602 new health care fraud investigations and had 2,771 pending investigations. Investigative efforts produced 730 criminal health care fraud convictions and 849 indictments and informations. In addition, investigative efforts resulted in over 605 operational disruptions of criminal fraud organizations and the dismantlement of the criminal hierarchy of more than 140 health care fraud criminal enterprises.

The FBI is the primary investigative agency involved in the fight against health care fraud that has jurisdiction over both the Federal and private insurance programs. Health care fraud investigations are considered a high priority within the FBI's Complex Financial Crime Program. Each of the 56 FBI field offices has personnel assigned specifically to investigate health care fraud matters.

The FBI leverages its resources in both the private and public arenas through investigative partnerships with other federal agencies such as HHS-OIG, the FDA, the DEA, the Defense Criminal Investigative Service, the Office of Personnel Management-OIG, the Internal Revenue Service-CI, state Medicaid Fraud Control Units, and other state and local agencies. On the private side, the FBI is actively involved in the Healthcare Fraud Prevention Partnership, an effort to exchange facts and information between the public and private sectors in order to reduce the prevalence of health care fraud. These efforts will enable members to share successful anti-fraud practices and effective methodologies and strategies for detecting and preventing health care fraud. In addition, the FBI maintains significant liaison with private insurance national groups, such as the National Health Care Anti-Fraud Association, the National Insurance Crime Bureau, and private insurance investigative units.

In addition to being a partner in the majority of investigations listed in the body of this report, FBI field offices throughout the U.S. have proactively addressed significant health care fraud threats through joint investigative efforts; intelligence collection, sharing, and analysis; and the utilization of advanced and sophisticated investigative techniques. Each FBI field office is involved in a health care fraud Task Force and/or working group. Members of the groups include U.S. Attorneys' Office and HHS-OIG personnel, and in many cases also include other federal, state, local, and private insurance personnel. Based on information sharing and coordination, additional cases are vetted and identified for investigation. These activities seek to identify and pursue investigations against the most egregious offenders involved in health care fraud and abuse, including criminal enterprises and other crime groups; corporations; companies; and providers whose schemes affect public safety.

In an effort to ensure sufficient FBI health care fraud resources are dedicated to address priority threats within the health care system for which the FBI has responsibility, the FBI provides oversight and guidance to field offices. The guidance has included three initiatives to combat the crime problem, including the Health Care Fraud Prevention & Enforcement Action Team (HEAT), Large Scale Conspiracies, and Major Provider Fraud.

A description of, and examples of results obtained by, the HEAT Initiative are contained in the body of this report. Contained within the HEAT section of the report is a description of, and examples of results obtained by, the Medicare Fraud Strike Forces, a key component of HEAT. The FBI coordinates with the DOJ and HHS-OIG on all HEAT aspects including funding, resource allocation, Strike Force expansion, target identification, training, and operations. The FBI has 62 agents assigned to the nine Strike Forces in Miami, New York City, Houston, Tampa, Detroit, Los Angeles, Southern Louisiana, Dallas, and Chicago. In addition to funding agent resources, the FBI funded undercover operation expenses, financial and investigative analysis support, offsite and evidence storage locations, and other investigative costs. These Strike Forces have effectively investigated and prosecuted individuals and entities that do not provide legitimate health care services, but exist solely for the purpose of defrauding Medicare and other Federal government health care programs. The continued support of Medicare Fraud Strike Force operations is a top priority for the FBI.

The Large Scale Conspiracies Initiative seeks to identify and target criminal enterprises and other groups whose schemes result in significant losses to health care benefit programs. Intelligence efforts for this initiative include information sharing and analysis of billing data with health care fraud enforcement partners. As the FBI continues to focus efforts on these groups, statistical accomplishments associated with the operational disruptions of criminal fraud organizations and the dismantlement of the criminal hierarchy of criminal enterprises have steadily increased. Investigative assistance provided to field offices as part of the initiative can include support for undercover operations, source identification and support, and funding of investigative costs. An example of these types of cases was the investigation into three community mental health centers – Shifa Community Mental Health Center of Baton Rouge, Serenity Center of Baton Rouge and Shifa Community Mental Health Center of Texas – which resulted in 17 convictions of individuals employed by the facilities, including therapists, marketers, administrators, owners and the medical director. The companies billed Medicare for partial hospitalization program services for the mentally ill which were unnecessary or never provided over a period of approximately seven years. The companies, collectively, submitted more than \$258 million in claims to Medicare for partial hospitalization program services during this period. Medicare paid approximately \$43.5 million on those claims. The FBI is committed to addressing this type of crime problem through the disruption, dismantlement and prosecution of those involved in criminal enterprises and other organized criminal activities.

The Major Provider Fraud Initiative seeks to identify and target corporations, companies, and other corporate-level groups involved in fraud schemes with significant billing to government and private healthcare benefit programs. The related schemes are frequently complex, challenging to identify, and can involve conduct that is nationwide in scope. Extensive resources and coordination are frequently required due to the complexity and scope of the schemes. Qui tams

(whistleblowers) are a significant intelligence source for these types of cases. These investigations frequently involve pharmaceutical manufacturers, hospital corporations, and regional or national home health agencies. In addition to the work completed at the field office level, and in response to this substantial threat, the FBI has established a centralized support team to provide investigative assistance on these cases nationwide. Examples of significant major provider investigations have included Omnicare Inc., the nation's largest provider of pharmaceuticals and pharmacy services to nursing homes, and Amedisys Inc. Omnicare agreed to pay \$124.2 million for allegedly offering improper financial incentives to skilled nursing facilities in return for their continued selection of Omnicare to supply drugs to elderly Medicare and Medicaid beneficiaries. Amedisys Inc. and its affiliates agreed to pay \$150 million to the federal government to resolve allegations they violated the FCA by submitting false home healthcare billings to the Medicare program. The FBI coordinates efforts against the crime problem with our law enforcement partners, such as DOJ components, HHS-OIG, and FDA.

The FBI actively provides training and guidance on health care matters. The FBI has teamed with the DOJ, HHS, and private insurance organizations to provide training in the priority threat areas of health care fraud. Funded training has included innovative methods of employing advanced investigative techniques; basic health care fraud training for FBI special agent and professional staff newly assigned to investigate health care fraud; and sessions on new and current health care fraud trends and issues. FBI personnel training opportunities included sessions offered by the FBI, other government agencies and the private sector. In FY 2014, more than 275 FBI health care fraud investigators and analysts received training. FBI personnel also conducted a wide range of training for external audiences, including personnel involved in the investigation of health care fraud matters and medical industry representatives.

Funding received by the FBI is used to pay direct and indirect personnel-related costs associated with the 797 funded positions. Funds not used directly for personnel matters, are used to provide operational support for health care fraud investigations, national initiatives, training, specialized equipment, expert witness testimony, and Strike Force operations.

Return on Investment Calculation

- The return on investment (ROI) for the HCFAC program is calculated by dividing the total monetary results to the Federal government (not including relator payments) by the annual appropriation for the HCFAC Account in a given year (not including portions of CMS funding dedicated to the Medicare Integrity Program, listed in the table on page 90).
- The monetary results include deposits and transfers to the Medicare Part A Trust Fund and the Treasury, as well as restitution and compensatory damages to Federal agencies.
- The HCFAC Account is made up of three funding sources: mandatory funding for HHS and DOJ, including HHS-OIG, appropriated through Section 1817(k)(3)(A) of the Social Security Act; mandatory funding for FBI activities appropriated through Section 1817(k)(3)(B) of the Social Security Act; and discretionary funding for the HCFAC Account appropriated through the annual Labor-HHS-Education appropriation.
- FBI mandatory HIPAA funding is included in ROI calculations given the important role the FBI plays in achieving the monetary results reflected in the HCFAC annual report and because that statute states that the funds are for the same purposes as the funds provided for HHS and DOJ under the Social Security Act, even though FBI spending and monetary results are not required to be reported per the statute.
- Only certain portions of discretionary HCFAC Account funding are included in the ROI calculation. All discretionary HCFAC funding for HHS-OIG and DOJ are included in the HCFAC report ROI since they spend their discretionary funding on the same types of activities that they support with mandatory funding. Only the portion of CMS Medicare discretionary HCFAC funding that supports law enforcement is included in the HCFAC report ROI. The remainder of CMS's HCFAC Medicare discretionary funding supports activities in the Medicare Integrity Program (MIP) that are included in the MIP ROI, which is calculated separately and outside of the HCFAC report. Impacts of CMS Medicaid and Medicare program integrity funding are included in a separate report.

Total Health Care Fraud and Abuse Control Resources

The table below sets forth HCFAC funding, by agency, for health care fraud and abuse control activities in FY 2014, including sequester reductions. The FBI also receives a stipulated amount of HIPAA funding for use in support of the Fraud and Abuse Control Program, which is shown below. Separately, CMS receives additional Mandatory Resources under the Medicare Integrity Program (section 1817(k)(4) of the Social Security Act). The inclusion of the activities supported with these funds is not required in this report, and this information is included for informational purposes.

Since 2009, Congress has also appropriated annual amounts to help carry out health care fraud and abuse control activities within DOJ and HHS. Those amounts are set forth as Discretionary Resources in the table below and the results of the efforts supported with these funds are contained within this report.

Mandatory Resources	Fiscal Year 2014
Office of Inspector General	\$184,979,155
Health and Human Services Wedge ¹	35,379,478
Medicare Integrity Program ²	858,345,774
<i>MIP/Medicare (non-add)</i>	792,319,176
<i>Medi-Medi (non-add)</i>	66,026,598
Department of Justice Wedge ¹	57,755,584
Federal Bureau of Investigation ³	127,318,870
Subtotal, Mandatory HCFAC	1,263,778,861
Discretionary Resources	
Office of Inspector General	28,122,000
CMS Program Integrity	237,344,000
<i>Medicare Program Integrity (Non-Add)</i>	207,636,000
<i>Medicaid Program Integrity (Non-Add)</i> ⁴	29,708,000
Department of Justice	28,122,000
Subtotal, Discretionary HCFAC	293,588,000
Grand Total, HCFAC	\$1,557,366,861

¹ The HHS and DOJ Wedge funds are divided among multiple agencies within HHS and DOJ. Page 7 of this report includes the allocations of the HHS and DOJ Wedge by agency or activity.

² Medicare Integrity Program (MIP) and Medi-Medi fund fraud prevention and detection activities within Medicare and Medicaid, which are not included in this report to Congress. There is another mandatory report due to Congress regarding MIP activities.

³ The FBI receives funding annually to conduct anti-fraud activities authorized by HIPAA. This funding is included in the HCFAC ROI calculation for this report.

⁴ This does not include the Medicaid Integrity Program authorized in the Deficit Reduction Act of 2005, which receives funding separately from the HCFAC account.

Glossary of Terms

The Account – The Health Care Fraud and Abuse Control Account

ACA – Affordable Care Act

AoA – Department of Health and Human Services, Administration on Aging

ACL – Department of Health and Human Services, Administration for Community Living

ASPA – Assistant Secretary for Public Affairs (HHS)

AUSA – Assistant United States Attorney

CHIP – Children’s Health Insurance Program

CIA – Corporate Integrity Agreement

CMP – Civil Monetary Penalty

CMPL – Civil Monetary Penalties Law

CMS – Department of Health and Human Services, Centers for Medicare & Medicaid Services

CNC – Compromised Number Contractors

CPI – Center for Program Integrity

CRIPA – Civil Rights of Institutionalized Persons Act

CY – Calendar Year

D.XX or X.D.Xx – Federal judicial district of a state, which may include north, south, east, west

DME – Durable Medical Equipment

DOJ – The Department of Justice

FEHBP – Federal Employee Health Benefits Program

FBI – Federal Bureau of Investigation

FCA – False Claims Act

FDA – Food and Drug Administration

FDCA – Food, Drug, and Cosmetic Act

FY – Fiscal Year

HCFAC – Health Care Fraud and Abuse Control Program or the Program

HEAT – Health Care Fraud Prevention & Enforcement Action Team

HFPP – Healthcare Fraud Prevention Partnership

HHA – Home Health Agency

HHS – The Department of Health and Human Services

HHS-OIG – The Department of Health and Human Services - Office of the Inspector General

HI – Hospital Insurance Trust Fund

HIPAA – The Health Insurance Portability and Accountability Act of 1996, P.L. 104-191

HIV – Human Immunodeficiency Virus

MEDIC – Medicare Drug Integrity Contractors

MFCU – Medicaid Fraud Control Unit

OCGS – Organized Crime and Gang Section

OGC – Office of the General Counsel, Department of Health and Human Services

PERM – Program Error Rate Measurement

PFP – Pharmaceutical Fraud Pilot Program

The Program – The Health Care Fraud and Abuse Control Program

Secretary – The Secretary of the Department of Health and Human Services

SMP – Senior Medicare Patrol

USAO – United States Attorney's Office

ZPIC – Zone Program Integrity Contractor

EXHIBIT I2

ChloroPrep® 1 mL applicator

Patient preoperative skin preparation
2% chlorhexidine gluconate (CHG) and 70% isopropyl alcohol (IPA)



Application instructions

Before using the ChloroPrep® 1 mL applicator, read the instructions on the package. Use in accordance with the policies and procedures of your hospital.



Pinch

- Hold the applicator with the sponge down. Do not touch the sponge.
- Pinch the wings **only once** to activate the ampoule and release the antiseptic.



Apply

- Allow the solution to partially load in the sponge. Gently press the applicator against the treatment area to evenly distribute the solution throughout the sponge.
- Once the solution is visible on the skin, completely wet the treatment area with antiseptic, using gentle back-and-forth strokes, progressing from the incision site to the periphery of the surgical field:
 - **For dry sites** (e.g., abdomen or arm):
Use gentle, repeated back-and-forth strokes for 30 seconds.
 - **For moist sites** (e.g., inguinal fold or axilla):
Use gentle, repeated back-and-forth strokes for two minutes.



Dry

- For dry surgical sites, allow the area to dry for approximately 30 seconds.
- For moist surgical sites, allow the area to dry for approximately one minute.
- Do not blot or wipe away the solution.
- The solution must be dry for optimal drape/dressing adhesion.



Catalog number

○ 260480 Clear

Approximate coverage area: 2.5x2.5"

60 applicators per carton, 4 cartons per case

Safety points for products containing alcohol

- Do not use with electrocautery.
- Do not allow the solution to pool.
- Remove wet materials from the prep area.

Additional information

- Use with care in premature infants or infants under two months of age. These products may cause irritation or chemical burns.
- Discard the applicator after a single use.
- Note that the applicator is latex-free and for external use.
- Use in a well-ventilated area.
- Do not use for lumbar puncture or in contact with the meninges.
- Do not use on open wounds or as a general skin cleanser.
- Do not use on patients with known allergies to CHG or IPA.
- Keep the solution out of the eyes, ears and mouth.
- Store between 15 to 30 °C (59 to 86 °F).
- Avoid freezing and excessive heat above 40 °C (104 °F). Store within the recommended conditions to maintain the appearance of tint and efficacy.

ChloroPrep representative: _____

In-service dates: _____

Time: _____

Reorder number: _____

Location of ChloroPrep applicators at this facility: _____

carefusion.com/chloraprep | 800.523.0502

ChloroPrep®

Patient preoperative skin preparation
2% chlorhexidine gluconate (CHG) and 70% isopropyl alcohol (IPA)

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EXHIBIT I3

SECTION 1: Identification of the substance/mixture and of the company/undertaking
1.1. Product identifier

 Product name : ChloroPrep[®] Solutions

1.2. Relevant identified uses of the substance or mixture and uses advised against

Use of the substance/mixture : Antimicrobial

1.3. Details of the supplier of the safety data sheet

 CareFusion
 75 N. Fairway Drive
 Vernon Hills, IL 60061
 T 800-523-0502 - F 855-329-6985

1.4. Emergency telephone number

Emergency number : Chemtrec 1 800 424 9300

SECTION 2: Hazards identification
2.1. Classification of the substance or mixture
GHS-US classification

 Flam. Liq. 2 H225
 Eye Irrit. 2A H319
 STOT SE 3 H336
 STOT SE 3 H335

2.2. Label elements
GHS-US labelling

Hazard pictograms (GHS-US) :



Signal word (GHS-US) :

: Danger

Hazard statements (GHS-US) :

 : H225 - Highly flammable liquid and vapor
 H319 - Causes serious eye irritation
 H335 - May cause respiratory irritation
 H336 - May cause drowsiness or dizziness

Precautionary statements (GHS-US) :

 : P210 - Keep away from heat/sparks/open flames/hot surfaces. - No smoking
 P233 - Keep container tightly closed
 P240 - Ground/bond container and receiving equipment
 P241 - Use explosion-proof electrical/ventilating/lighting/... equipment
 P242 - Use only non-sparking tools
 P243 - Take precautionary measures against static discharge
 P261 - Avoid breathing dust/fume/gas/mist/vapors/spray
 P264 - Wash ... thoroughly after handling
 P271 - Use only outdoors or in a well-ventilated area
 P280 - Wear protective gloves/protective clothing/eye protection/face protection
 P303+P361+P353 - IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower
 P304+P340 - IF INHALED: remove victim to fresh air and keep at rest in a position comfortable for breathing
 P305+P351+P338 - If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
 P312 - Call a POISON CENTER/doctor/physician if you feel unwell
 P337+P313 - If eye irritation persists: Get medical advice/attention
 P370+P378 - In case of fire: Use ... for extinction
 P403+P233 - Store in a well-ventilated place. Keep container tightly closed
 P403+P235 - Store in a well-ventilated place. Keep cool
 P405 - Store locked up
 P501 - Dispose of contents/container to ...

ChloroPrep® Solutions

Safety Data Sheet

2.3. Other hazards

No additional information available

2.4. Unknown acute toxicity (GHS-US)

No data available

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

Full text of H-phrases: see section 16

3.2. Mixture

ChloroPrep® Clear

Name	Product identifier	%	GHS-US classification
Isopropyl alcohol	(CAS No) 67-63-0	70	Flam. Liq. 2, H225
Chlorhexidine digluconate	(CAS No) 18472-51-0	2	Acute Tox. 4 (Oral), H302

ChloroPrep® Teal Green

Name	Product identifier	%	GHS-US classification
Isopropyl alcohol	(CAS No) 67-63-0	70	Flam. Liq. 2, H225
Chlorhexidine digluconate	(CAS No) 18472-51-0	2	Acute Tox. 4 (Oral), H302
C.I. Food Green 3	(CAS No) 2353-45-9	0 - 0.1	Muta. 2, H341

ChloroPrep® Hi-Lite Orange

Name	Product identifier	%	GHS-US classification
Isopropyl alcohol	(CAS No) 67-63-0	70	Flam. Liq. 2, H225
Chlorhexidine digluconate	(CAS No) 18472-51-0	2	Acute Tox. 4 (Oral), H302
FD and C Yellow No. 6	(CAS No) 2783-94-0	0 - 0.1	Not classified

SECTION 4: First aid measures

4.1. Description of first aid measures

- First-aid measures after inhalation : If symptoms of exposure develop, move to fresh air. Seek medical attention if symptoms persist.
- First-aid measures after skin contact : Wash material off the skin with copious amounts of water. If redness or a burning sensation develops, seek medical attention and discontinue use.
- First-aid measures after eye contact : Flush with copious amounts of water. After initial flushing remove any contact lenses and continue flushing for at least 15minutes. Have eyes examined and treated by medical personnel immediately.
- First-aid measures after ingestion : Give individual one to two glasses of water to drink. If gastrointestinal symptoms develop, consult medical personnel. (Never give anything by mouth to an unconscious person).

4.2. Most important symptoms and effects, both acute and delayed

- Symptoms/injuries after inhalation : Inhalation of vapors may cause mucous membrane and respiratory irritation and central nervous system depression with symptoms of headache, dizziness and drowsiness.
- Symptoms/injuries after skin contact : May cause irritation, drying, defatting of the skin. Prolonged contact may cause dermatitis.
- Symptoms/injuries after eye contact : Contact may cause severe irritation with redness, tearing and pain with possible eye damage.
- Symptoms/injuries after ingestion : Ingestion may cause mucous membrane and gastrointestinal irritation, abdominal pain, nausea, vomiting, dizziness and drowsiness.

4.3. Indication of any immediate medical attention and special treatment needed

No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media

- Suitable extinguishing media : Water fog, alcohol-resistant foam, carbon dioxide or dry chemical. Water spray can be used to cool exposed containers and structures, dilute spills and disperse flammable vapors.
- Unsuitable extinguishing media : None.

5.2. Special hazards arising from the substance or mixture

- Fire hazard : Highly flammable liquid and vapor. Ampoules may explode if exposed to extreme heat or flame. Vapors are heavier than air and will travel along surfaces to remote ignition sources and flash back.
- Explosion hazard : None known.

ChloroPrep[®] Solutions

Safety Data Sheet

5.3. Advice for firefighters

Protection during firefighting : Firefighters should wear positive pressure self-contained breathing apparatus and full protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : No special measures required.

6.1.1. For non-emergency personnel

No additional information available

6.1.2. For emergency responders

No additional information available

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

For containment : Stop the flow of material, if this is without risk.

Methods for cleaning up : Wear skin, eye and respiratory protection during cleanup. For small spills, wipe or mop up and rinse to sewer serviced by a wastewater treatment facility. For large spills, eliminate sources of ignition and ventilate spill area. Soak up liquid with inert absorbent and collect into a suitable waste container. Wash residue from spill area with water and flush to sewer serviced by a wastewater treatment facility if permitted.

6.4. Reference to other sections

No additional information available

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Avoid prolonged exposure (ingestion, inhalation, or skin contact). Avoid breathing vapors. Use in well-ventilated areas. Keep product away from heat, sparks and flames.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in a cool, dry, well-ventilated area away from incompatible chemicals and all sources of ignition.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Isopropyl alcohol (67-63-0)		
USA ACGIH	ACGIH TWA (ppm)	200 ppm
USA ACGIH	ACGIH STEL (ppm)	400 ppm
USA OSHA	OSHA PEL (TWA) (mg/m ³)	980 mg/m ³
USA OSHA	OSHA PEL (TWA) (ppm)	400 ppm

8.2. Exposure controls

Appropriate engineering controls : Use with adequate general or local exhaust ventilation to maintain exposures below the occupational exposure limits. Use explosion proof equipment where required.

Hand protection : Latex rubber for limited contact. Butyl rubber or nitrile recommended for prolonged contact.

Eye protection : Safety glasses or goggles recommended if eye contact is possible.

Skin and body protection : Wear suitable working clothes.

Respiratory protection : If the exposure limits are exceeded a NIOSH/EN approved organic vapor respirator appropriate for the form and concentration of the contaminants should be used.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Liquid

Appearance : Clear in product; when activated, clear orange, teal

ChloroPrep® Solutions

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Color	: Clear, orange, or teal
Odor	: Odorless
Odor threshold	: No data available
pH	: 7 - 7.5
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: No data available
Freezing point	: No data available
Boiling point	: No data available
Flash point	: 67 °F
Self ignition temperature	: 2 - 12.7
Decomposition temperature	: No data available
Flammability (solid, gas)	: No data available
Vapor pressure	: No data available
Relative vapor density at 20 °C	: No data available
Specific gravity	: 0.88
Solubility	: Water: Complete
Log Pow	: No data available
Log Kow	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidizing properties	: No data available
Explosive limits	: No data available

9.2. Other information

VOC content : 100 %

SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available

10.2. Chemical stability

The product is stable at normal handling and storage conditions.

10.3. Possibility of hazardous reactions

Will not occur.

10.4. Conditions to avoid

Extreme heat, sparks or flame.

10.5. Incompatible materials

Oxidizing materials

10.6. Hazardous decomposition products

Carbon dioxide, carbon monoxide, nitrogen oxides, ammonia, chlorine compounds.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Not classified

Isopropyl alcohol (67-63-0)	
LD50 oral rat	4396 mg/kg
LD50 dermal rabbit	12800 mg/kg
LC50 inhalation rat (ppm)	16000 ppm (Exposure time: 8 h)

Chlorhexidine digluconate (18472-51-0)	
ATE (oral)	500.000 mg/kg

Skin corrosion/irritation : Not classified

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Serious eye damage/irritation	: Causes serious eye irritation.
Respiratory or skin sensitisation	: Not classified
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified

Isopropyl alcohol (67-63-0)	
IARC group	3 - Not classifiable

C.I. Food Green 3 (2353-45-9)	
IARC group	3 - Not classifiable

FD and C Yellow No. 6 (2783-94-0)	
IARC group	3 - Not classifiable

Reproductive toxicity	: Not classified
Specific target organ toxicity (single exposure)	: May cause drowsiness or dizziness. May cause respiratory irritation.
Specific target organ toxicity (repeated exposure)	: Not classified
Aspiration hazard	: Not classified

SECTION 12: Ecological information

12.1. Toxicity

Isopropyl alcohol (67-63-0)	
LC50 fishes 1	9640 mg/l (Exposure time: 96 h - Species: Pimephales promelas [flow-through])
EC50 Daphnia 1	13299 mg/l (Exposure time: 48 h - Species: Daphnia magna)
EC50 other aquatic organisms 1	> 1000 mg/l (Exposure time: 96 h - Species: Desmodesmus subspicatus)
LC50 fish 2	11130 mg/l (Exposure time: 96 h - Species: Pimephales promelas [static])
EC50 other aquatic organisms 2	> 1000 mg/l (Exposure time: 72 h - Species: Desmodesmus subspicatus)

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

Isopropyl alcohol (67-63-0)	
Log Pow	0.05 (at 25 °C)

12.4. Mobility in soil

No additional information available

12.5. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste disposal recommendations : Dispose of contents/container in accordance with local/regional/national/international regulations.

SECTION 14: Transport information

In accordance with DOT

Transport document description	: UN1219 Isopropanol Solution, 3, II
UN-No.(DOT)	: 1219
DOT NA no.	: UN1219
DOT Proper Shipping Name	: Isopropanol Solution
Department of Transportation (DOT) Hazard Classes	: 3 - Class 3 - Flammable and combustible liquid 49 CFR 173.120

ChloroPrep® Solutions

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Hazard labels (DOT) : 3 - Flammable liquid



Packing group (DOT) : II - Medium Danger

DOT Special Provisions (49 CFR 172.102) : IB2 - Authorized IBCs: Metal (31A, 31B and 31N); Rigid plastics (31H1 and 31H2); Composite (31HZ1). Additional Requirement: Only liquids with a vapor pressure less than or equal to 110 kPa at 50 C (1.1 bar at 122 F), or 130 kPa at 55 C (1.3 bar at 131 F) are authorized.
T4 - 2.65 178.274(d)(2) Normal..... 178.275(d)(3)
TP1 - The maximum degree of filling must not exceed the degree of filling determined by the following: Degree of filling = $97 / (1 + a (tr - tf))$ Where: tr is the maximum mean bulk temperature during transport, and tf is the temperature in degrees celsius of the liquid during filling.

DOT Packaging Exceptions (49 CFR 173.xxx) : 4b;150

DOT Packaging Non Bulk (49 CFR 173.xxx) : 202

DOT Packaging Bulk (49 CFR 173.xxx) : 242

DOT Quantity Limitations Passenger aircraft/rail (49 CFR 173.27) : 5 L

DOT Quantity Limitations Cargo aircraft only (49 CFR 175.75) : 60 L

DOT Vessel Stowage Location : B - (i) The material may be stowed "on deck" or "under deck" on a cargo vessel and on a passenger vessel carrying a number of passengers limited to not more than the larger of 25 passengers, or one passenger per each 3 m of overall vessel length; and (ii) "On deck only" on passenger vessels in which the number of passengers specified in paragraph (k)(2)(i) of this section is exceeded.

SECTION 15: Regulatory information

15.1. US Federal regulations

Isopropyl alcohol (67-63-0)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
Listed on SARA Section 313 (Specific toxic chemical listings)	
EPA TSCA Regulatory Flag	T - T - indicates a substance that is the subject of a Section 4 test rule under TSCA.
SARA Section 313 - Emission Reporting	1.0 % (only if manufactured by the strong acid process, no supplier notification)
C.I. Food Green 3 (2353-45-9)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
Chlorhexidine digluconate (18472-51-0)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
FD and C Yellow No. 6 (2783-94-0)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	

15.2. US State regulations

Isopropyl alcohol (67-63-0)
U.S. - Massachusetts - Right To Know List
U.S. - Minnesota - Hazardous Substance List
U.S. - New Jersey - Right to Know Hazardous Substance List
U.S. - Pennsylvania - RTK (Right to Know) List

SECTION 16: Other information

Full text of H-phrases:

Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Eye Irrit. 2A	Serious eye damage/eye irritation, Category 2A
Flam. Liq. 2	Flammable liquids, Category 2
Muta. 2	Germ cell mutagenicity, Category 2
STOT SE 3	Specific target organ toxicity — Single exposure, Category 3, Narcosis

ChloroPrep[®] Solutions

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STOT SE 3	Specific target organ toxicity — Single exposure, Category 3, Respiratory tract irritation
H225	Highly flammable liquid and vapor
H302	Harmful if swallowed
H319	Causes serious eye irritation
H335	May cause respiratory irritation
H336	May cause drowsiness or dizziness
H341	Suspected of causing genetic defects

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product

EXHIBIT I4

ChloroShield® IV dressing with CHG antimicrobial

Protect and preserve IV access sites with an innovative adhesive technology

The ChloroShield® IV dressing with chlorhexidine gluconate (CHG) antimicrobial was designed with the patient and clinician in mind. For patients, the dressing is flexible and breathable, providing comfort during wear. For clinicians, the adhesive has CHG incorporated, and the dressing is designed to deliver optimized fluid management, protecting the site and enhancing patient care.



ChloraShield IV dressing features include:

- **BeneHold™ CHG adhesive technology by Vancive Medical Technologies™**
 - Offers thin, strong adhesive to secure the dressing to the skin for up to seven days¹
 - CHG within the adhesive preserves the dressing from microbial growth²
 - Proprietary formulation that can wick away and absorb fluid³
- **Transparent film with CHG incorporated in the adhesive over a large area**
 - Allows site visibility and becomes fully transparent for ongoing inspection
 - Allows vapor exchange and release of absorbed fluid³
 - Provides a barrier to external contaminants including fluids, bacteria, viruses* and yeast⁴
- **Built-in data strip**
 - Facilitates documentation pre- or post-application
 - Eliminates an extra application step
 - Denotes the dressing contains CHG

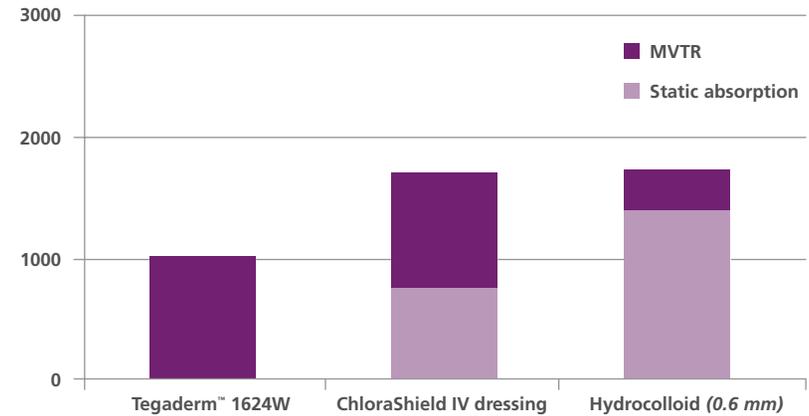
References

¹ Wear test study on healthy human S13-19 ² Bacteria time kill study R31476-R0

³ Report aw\31012014-1 ⁴ Viral penetration test ASTM F-1671

* From viruses 27 nm in diameter or larger

Fluid handling capacity (g/m²/24 h)



ChloraShield IV dressing with CHG antimicrobial manages more fluid than current commercial hydrocolloid or transparent film dressing.³

Ordering information

Description	ChloraShield IV dressing with CHG antimicrobial
Cat. no.	410150
Size	3.0 in x 2.4 in (75 mm x 60 mm)
Qty. per carton	200 dressings
Cartons per case	10 cartons

For more information about the ChloraShield IV dressing with CHG antimicrobial, contact CareFusion Customer Service at **800.523.0502**.

Distributed by:
CareFusion
Vernon Hills, IL

carefusion.com

Manufactured by:
Avery Dennison België BVBA
Tieblokkenlaan 1, B-2300 Turnhout, Belgium

vancive.averydennison.com

EXHIBIT I5

ChloroPrep® patient preoperative skin preparation

Nonsterile solution label update

Prep for a label change

To improve clinician awareness and patient safety, updated ChloroPrep® patient preoperative skin preparation labels communicate that the solution is nonsterile.

Background

In 2013, the U.S. Food and Drug Administration (FDA) requested that manufacturers of over-the-counter topical antiseptics make changes to their products in an ongoing effort to improve patient safety. The modifications included a request that manufacturers use single-use packaging and revise the product labels to indicate whether the antiseptic solution and applicator contained within the product is sterile or nonsterile.

A sterile applicator with nonsterile solution

A product labeled as nonsterile does not suggest the product is contaminated with microorganisms; instead, its contents have not been sterilized individually. While all ChloroPrep applicators are sterilized at the end of the manufacturing process, the solution inside the applicators is not treated with a separate sterilization process and is, therefore, not sterile.

There are currently no products in the U.S. that contain a chlorhexidine gluconate (CHG)-based sterile solution—only sterile applicators.

Quality Assurance

ChloroPrep® patient preoperative skin preparation products have never been documented as the cause of contamination causing patient infection. The safety and consistency of ChloroPrep is guaranteed through well-designed and controlled manufacturing and testing procedures including chemical analysis, microbial analysis, applicator integrity reviews and package testing. These steps ensure that each ChloroPrep applicator will consistently perform as intended.



The AORN Seal of Recognition has been awarded to the CareFusion - CHP Label change program on February 20, 2015 and does not imply that AORN approves or endorses any product or service mentioned in any presentation, format or content. The AORN Recognition program is separate from the AORN, ANCC Accredited Provider Unit and therefore does not include any CE credit for programs.



CareFusion

<p>⚠ WARNING FLAMMABLE</p> <p>Keep away from fire or flame. To reduce risk of fire, PREP CAREFULLY:</p> <ul style="list-style-type: none">do not use 26-ml applicator for head and neck surgery or on an area smaller than 8.4 in. x 8.4 in. Use a smaller applicator instead.solution contains alcohol and gives offavoid getting solution into hairy areas. Hair may take up to 1 hour to dry.do not drape or use ignition source (e.g., cautery, laser) until solution is completely dry (minimum of 3 minutes on hairless skin; up to 1 hour in hair)do not allow solution to poolremove wet materials from prep area	<p>ChloroPrep® One-Step ChloroPrep® With Tint</p> <p>2% w/v chlorhexidine gluconate (CHG) and 70% v/v isopropyl alcohol (IPA) Patient Preoperative Skin Preparation Non-sterile Solution Applicator is sterile if package is intact 26 ml APPLICATOR</p> <p>Professional Use Only Do Not Reuse Not made with natural rubber latex</p> <p>Cat. No. 260800 / 260800NS / 260800NSB NDC 054365-400-14 Cat. No. 260815 / 260815NS / 260815NSB NDC 054365-400-13 Cat. No. 260825 / 260825NS / 260825NSB NDC 054365-400-05</p>						
<p>Drug Facts</p> <table border="1"><thead><tr><th>Active ingredients</th><th>Purposes</th></tr></thead><tbody><tr><td>Chlorhexidine gluconate 2% w/v</td><td>Antiseptic</td></tr><tr><td>Isopropyl alcohol 70% v/v</td><td>Antiseptic</td></tr></tbody></table> <p>Use for the preparation of the patient's skin prior to surgery. Helps to reduce bacteria that potentially can cause skin infection.</p> <p>Warnings</p> <p>For external use only. Flammable, keep away from fire or flame. To reduce risk of fire, PREP CAREFULLY:</p> <ul style="list-style-type: none">do not use 26-ml applicator for head and neck surgerydo not use on an area smaller than 8.4 in. x 8.4 in. Use a smaller applicator insteadsolution contains alcohol and gives offavoid getting solution into hairy areas. Hair may take up to 1 hour to dry.do not drape or use ignition source (e.g., cautery, laser) until solution is completely dry (minimum of 3 minutes on hairless skin; up to 1 hour in hair)do not allow solution to poolremove wet materials from prep area	Active ingredients	Purposes	Chlorhexidine gluconate 2% w/v	Antiseptic	Isopropyl alcohol 70% v/v	Antiseptic	
Active ingredients	Purposes						
Chlorhexidine gluconate 2% w/v	Antiseptic						
Isopropyl alcohol 70% v/v	Antiseptic						

"Nonsterile solution" label update

In response to the industry-wide request from the Food and Drug Administration (FDA), ChloroPrep patient preoperative skin preparation will be among the first chlorhexidine gluconate (CHG) based products to update its product label "nonsterile solution."

Labels will be updated on the applicators in the ChloroPrep portfolio:

Cat. no.	Applicator
260100	Single swabstick 1.75 mL
260103	Triple swabstick 5.25 mL
260449	SEPP® applicator
260480	1 mL clear applicator
260299	FREPP® 1.5 mL clear applicator
260400	3 mL clear applicator
260415	3 mL Hi-Lite Orange® tint
260700	10.5 mL clear applicator
260715	10.5 mL Hi-Lite Orange tint
260725	10.5 mL Scrub Teal® tint
260800	26 mL clear applicator
260815	26 mL Hi-Lite Orange tint
260825	26 mL Scrub Teal tint



The same antiseptis solution

While CareFusion is updating its label, the ChloroPrep patient preoperative skin preparation formulation, patented applicator design or single-use packaging have not changed. ChloroPrep continues to be the trusted one-step, broad spectrum antiseptic that reduces microorganisms on the skin that can cause infection.

Contact your sales representative or call customer support at **800.323.9088**.

Learn more at carefusion.com/labelupdate.

CareFusion
Vernon Hills, IL

carefusion.com



EXHIBIT I6

ChloroPrep® 3 mL applicator

Patient preoperative skin preparation
2% chlorhexidine gluconate (CHG) and 70% isopropyl alcohol (IPA)



Application instructions



Pinch

- Hold the applicator with the sponge down. Do not touch the sponge.
- Pinch the wings **only once** to activate the ampoule and release the antiseptic.



Apply

- Allow the solution to partially load in the sponge. Gently press the applicator against the treatment area to evenly distribute the solution throughout the sponge.
- Once the solution is visible on the skin, completely wet the treatment/incision area with the antiseptic, using gentle back-and-forth strokes for 30 seconds or two minutes, progressing from the incision site to the periphery of the surgical field:
 - **For dry sites** (e.g., abdomen or arm): Use gentle, repeated back-and-forth strokes for 30 seconds.
 - **For moist sites** (e.g., inguinal fold or axilla): Use gentle, repeated back-and-forth strokes for two minutes.



Dry

- For dry surgical sites, allow the area to dry for approximately 30 seconds.
- For moist surgical sites, allow the area to dry for approximately one minute.
- Do not blot or wipe away the solution.
- The solution must be dry for optimal drape/dressing adhesion.
- If using an ignition source, allow the area to completely dry (*minimum of three minutes on hairless skin; up to 1 hour in hair*).

Before using the ChloroPrep 3 mL applicator, read the instructions on the package. Use in accordance with the policies and procedures of your hospital.

Catalog numbers



- 260400 Clear
- 260415 Hi-Lite Orange®

Approximate coverage area: 4" x 5"
25 applicators per carton,
4 cartons per case

Safety points for products containing alcohol

- Do not drape or use an ignition source (e.g., cautery, laser) until the solution is completely dry for a minimum of three minutes on hairless skin and up to one hour in hair.
- Do not allow the solution to pool.
- Remove wet materials from the prep area.

ChloroPrep® tint

- Hi-Lite Orange tint in the ChloroPrep solution is Food, Drug and Cosmetic (FD&C) Yellow #6 dye, and "Generally Recognized As Safe" (GRAS) by the Food and Drug Administration (FDA). The tint eases visualization on various skin tones.
- Post-procedure, the tint slowly fades from the skin. To remove the tint, use soap and water or alcohol. The ChloroPrep patient preoperative skin preparation may remain on the skin post-procedure.

Additional information

- Use with care in premature infants or infants under 2 months of age. These products may cause irritation or chemical burns.
- Discard the applicator after a single use.
- Note that the applicator is latex-free and for external use.
- Use in a well-ventilated area.
- Do not use for lumbar puncture or in contact with the meninges.
- Do not use on open wounds or as a general skin cleanser.
- Do not use on patients with known allergies to CHG or IPA.
- Keep the solution out of the eyes, ears and mouth.
- Store between 15 to 30 °C (59 to 86 °F).
- Avoid freezing and excessive heat above 40 °C (104 °F). Store within the recommended conditions to maintain the appearance of tint and efficacy.

ChloroPrep representative: _____

In-service dates: _____

Time: _____

Reorder #: _____

Location of ChloroPrep applicators at this facility: _____

carefusion.com/chloraprep | 800.523.0502

ChloroPrep®

Patient preoperative skin preparation
2% chlorhexidine gluconate (CHG) and 70% isopropyl alcohol (IPA)

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EXHIBIT I7

ChloraPrep® 10.5 mL applicator

Patient preoperative skin preparation
2% chlorhexidine gluconate (CHG) and 70% isopropyl alcohol (IPA)



Application instructions



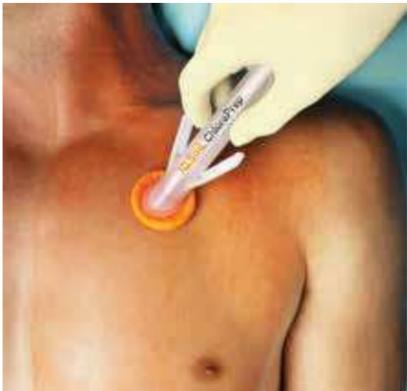
Pinch

- Hold the applicator with the sponge down. Do not touch the sponge.
- Pinch the wings **only once** to activate the ampoule and release the antiseptic.



Apply

- Allow the solution to partially load in the sponge. Gently press the applicator against the treatment area to evenly distribute the solution throughout the sponge.
- Once the solution is visible on the skin, completely wet the treatment/incision area with the antiseptic, using gentle back-and-forth strokes for 30 seconds or two minutes, progressing from the incision site to the periphery of the surgical field:
 - **For dry sites** (e.g., abdomen or arm): Use gentle, repeated back-and-forth strokes for 30 seconds.
 - **For moist sites** (e.g., inguinal fold or axilla): Use gentle, repeated back-and-forth strokes for two minutes.



Dry

- Allow the solution to completely dry for a minimum of three minutes on hairless skin and up to one hour in hair.
- Do not blot or wipe away the solution.
- The solution must be dry for optimal drape/dressing adhesion.

Before using the ChloraPrep 10.5 mL applicator, read the instructions on the package. Use in accordance with the policies and procedures of your hospital.

Catalog numbers

- 260700 Clear
- 260715 Hi-Lite Orange®
- 260725 Scrub Teal®

Approximate coverage area: 8.4" x 8.4"
25 applicators per carton,



Safety points for products containing alcohol

- Do not drape or use an ignition source (e.g., cautery, laser) until the solution is completely dry for a minimum of three minutes on hairless skin and up to one hour in hair.
- Do not allow the solution to pool.
- Remove wet materials from the prep area.

ChloraPrep® tint

- Hi-Lite Orange® tint in the ChloraPrep solution is Food, Drug and Cosmetic (FD&C) Yellow #6 dye, and the Scrub Teal® tint is FD&C Green #3. Both are "Generally Recognized As Safe" (GRAS) by the Food and Drug Administration (FDA). The tint eases visualization on various skin tones.
- Post-procedure, the tint slowly fades from the skin. To remove the tint, use soap and water or alcohol. The ChloraPrep patient preoperative skin preparation may remain on the skin post-procedure.

Additional information

- Use with care in premature infants or infants under 2 months of age. These products may cause irritation or chemical burns.
- Discard the applicator after a single use.
- Note that the applicator is latex-free and for external use.
- Use in a well-ventilated area.
- Do not use for lumbar puncture or in contact with the meninges.
- Do not use on open wounds or as a general skin cleanser.
- Do not use on patients with known allergies to CHG or IPA.
- Keep the solution out of the eyes, ears and mouth.
- Store between 15 to 30 °C (59 to 86 °F).
- Avoid freezing and excessive heat above 40 °C (104 °F). Store within the recommended conditions to maintain the appearance of tint and efficacy.

ChloraPrep representative: _____

In-service dates: _____

Time: _____

Reorder #: _____

Location of ChloraPrep applicators at this facility: _____

carefusion.com/chloraprep | 800.523.0502

ChloraPrep®

Patient preoperative skin preparation
2% chlorhexidine gluconate (CHG) and 70% isopropyl alcohol (IPA)

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EXHIBIT I8

ChloraPrep® 26 mL applicator

Patient preoperative skin preparation
2% chlorhexidine gluconate (CHG) and 70% isopropyl alcohol (IPA)

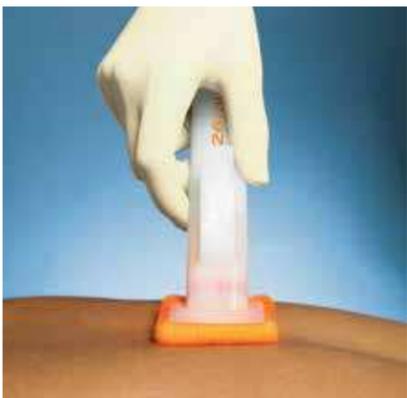


Application instructions



Pinch

- Hold the applicator with the sponge down. Do not touch the sponge.
- Pinch the lever **only once** to activate the ampoule and release the antiseptic.



Apply

- Allow the solution to partially load in the sponge. Gently press the applicator against the treatment area to evenly distribute the solution throughout the sponge.
- Once the solution is visible on the skin, completely wet the treatment/incision area with the antiseptic, using gentle back-and-forth strokes for 30 seconds or two minutes, progressing from the incision site to the periphery of the surgical field:
 - **For dry sites** (e.g., abdomen or arm): Use gentle, repeated back-and-forth strokes for 30 seconds.
 - **For moist sites** (e.g., inguinal fold or axilla): Use gentle, repeated back-and-forth strokes for two minutes.



Dry

- Allow the solution to completely dry for a minimum of three minutes on hairless skin and up to one hour in hair.
- Do not blot or wipe away the solution.
- The solution must be dry for optimal drape/dressing adhesion.

Before using the ChloraPrep 26 mL applicator, read the instructions on the package. Use in accordance with the policies and procedures of your hospital.



Catalog numbers

- 260800 Clear
- 260815 Hi-Lite Orange®
- 260825 Scrub Teal®

Approximate coverage area: 13.2" x 13.2"
25 applicators per case

Safety points for products containing alcohol

- Do not drape or use an ignition source (e.g., cautery, laser) until the solution is completely dry for a minimum of three minutes on hairless skin and up to one hour in hair.
- Do not allow the solution to pool.
- Remove wet materials from the prep area.

ChloraPrep® tint

- Hi-Lite Orange® tint in the ChloraPrep solution is Food, Drug and Cosmetic (FD&C) Yellow #6 dye, and the Scrub Teal® tint is FD&C Green #3. Both are "Generally Recognized As Safe" (GRAS) by the Food and Drug Administration (FDA). The tint eases visualization on various skin tones.
- Post-procedure, the tint slowly fades from the skin. To remove the tint, use soap and water or alcohol. The ChloraPrep patient preoperative skin preparation may remain on the skin post-procedure.

Additional information

- Use with care in premature infants or infants under 2 months of age. These products may cause irritation or chemical burns.
- Discard the applicator after a single use.
- Note that the applicator is latex-free and for external use.
- Use in a well-ventilated area.
- Do not use for lumbar puncture or in contact with the meninges.
- Do not use on open wounds or as a general skin cleanser.
- Do not use on patients with known allergies to CHG or IPA.
- Keep the solution out of the eyes, ears and mouth.
- Store between 15 to 30 °C (59 to 86 °F).
- Avoid freezing and excessive heat above 40 °C (104 °F). Store within the recommended conditions to maintain the appearance of tint and efficacy.

ChloraPrep representative: _____

In-service dates: _____

Time: _____

Reorder #: _____

Location of ChloraPrep applicators at this facility: _____

carefusion.com/chloraprep | 800.523.0502

ChloraPrep®

Patient preoperative skin preparation
2% chlorhexidine gluconate (CHG) and 70% isopropyl alcohol (IPA)

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EXHIBIT I9

Using ChloraPrep® 26 mL applicator prior to a Cesarean section

Patient preoperative skin preparation
2% chlorhexidine gluconate (CHG) and 70% isopropyl alcohol (IPA)

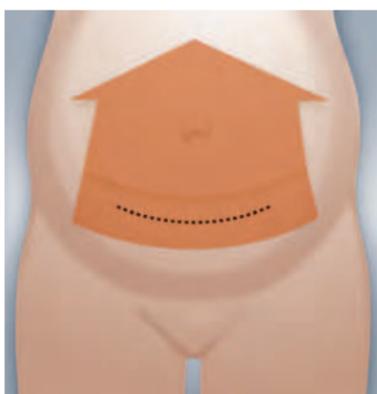


Application instructions



Pinch

- Hold the applicator with the sponge down. Do not touch the sponge.
- Pinch the lever **only once** to activate the ampoule and release the antiseptic.



Apply

- Allow the solution to partially load in the sponge. Gently press the applicator against the treatment area to evenly distribute the solution throughout the sponge.
- To clean the umbilicus, use the cotton swabs provided in accordance with aseptic technique.
- Once the solution is visible on the skin, completely wet the treatment/incision area with antiseptic, using gentle back-and-forth strokes, for 30 seconds or two minutes, progressing from the incision site to the periphery of the surgical field:
 - **For dry sites** (e.g., abdomen or arm): Use gentle, repeated back-and-forth strokes for 30 seconds
 - **For moist sites** (e.g., inguinal fold or axilla): Use gentle, repeated back-and-forth strokes for two minutes
- Prep the external peripheral area last, and discard the applicator.



Do not use intravaginally.

Dry

- Allow the solution to completely dry for a minimum of three minutes on hairless skin and up to one hour in hair.
- Do not blot or wipe away the solution.
- The solution must be dry for optimal drape/dressing adhesion.

Before using the ChloraPrep 26 mL applicator, read the instructions on the package. Use in accordance with the policies and procedures of your hospital.

carefusion.com/ChlorPrep | 800.523.0502

Catalog numbers



- 260800 Clear
- 260815 Hi-Lite Orange®
- 260825 Scrub Teal®

Approximate coverage area: 13.2" x 13.2"
25 applicators per case

Safety points for products containing alcohol

- Do not drape or use an ignition source (e.g., cautery, laser) until the solution is completely dry for a minimum of three minutes on hairless skin and up to one hour in hair.
- Do not allow the solution to pool.
- Remove wet materials from the prep area.
- When prepping the abdomen for a Cesarean section, place towels under each side to absorb excess solution. Remove these towels before draping.

ChloraPrep® tint

- Hi-Lite Orange® tint in the ChloraPrep solution, is Food, Drug and Cosmetic (FD&C) Yellow #6 dye, and the Scrub Teal® tint is FD&C Green #3. Both are "Generally Recognized As Safe" (GRAS) by the Food and Drug Administration (FDA). The tint eases visualization on various skin tones.
- Post-procedure, the tint slowly fades from the skin. To remove the tint, use soap and water or alcohol. The ChloraPrep patient preoperative skin preparation may remain on the skin post-procedure.

Additional information

- Use with care in premature infants or infants under 2 months of age. These products may cause irritation or chemical burns.
- Discard the applicator after a single use.
- Note that the applicator is latex-free and for external use.
- Use in a well-ventilated area.
- Do not use for lumbar puncture or in contact with the meninges.
- Do not use on open skin wounds or as a general skin cleanser.
- Do not use on patients with known allergies to CHG or IPA.
- Keep the solution out of the eyes, ears and mouth.
- Store between 15 to 30 °C (59 to 86 °F).
- Avoid freezing and excessive heat above 40 °C (104 °F). Store within the recommended conditions to maintain the appearance of tint and efficacy.

ChlorPrep®

Patient preoperative skin preparation
2% chlorhexidine gluconate (CHG) and 70% isopropyl alcohol (IPA)

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EXHIBIT I10

ChloroPrep® FREPP® 1.5 mL applicator

Patient preoperative skin preparation
2% chlorhexidine gluconate (CHG) and 70% isopropyl alcohol (IPA)



Application instructions



Pinch

- Hold the applicator horizontally with the sponge down. Do not touch the sponge.
- Pinch the wings **only once** to activate the enclosed glass ampoule and release the antiseptic into the sponge.



Apply

- Holding the applicator horizontally, allow the solution to partially load in the sponge. Gently press the applicator against the treatment area to evenly distribute the solution throughout the sponge.
- Once the solution is visible on the skin, completely wet the treatment area with antiseptic, using gentle back-and-forth strokes, progressing from the procedure site to the periphery:
 - **For dry sites** (e.g., abdomen or arm): Use gentle, repeated back-and-forth strokes for 30 seconds.
 - **For moist sites** (e.g., inguinal fold or axilla): Use gentle, repeated back-and-forth strokes for two minutes.



Dry

- For dry surgical sites, allow the area to dry for approximately 30 seconds.
- For moist surgical sites, allow the area to dry for approximately one minute.
- Do not blot or wipe away the solution.
- The solution must be dry for optimal drape/dressing adhesion.

Before using the ChloroPrep FREPP 1.5 mL applicator, read the instructions on the package. Use in accordance with the policies and procedures of your hospital.

Catalog number



260299

Approximate coverage area: 2.5" x 2.5"
20 applicators per carton,
25 cartons per case

Important safety points

- **Do not repeatedly pinch or pump the wings in an attempt to accelerate the saturation of the foam.**

Safety points for products containing alcohol

- Do not use with electrocautery.
- Do not allow the solution to pool.
- Remove wet materials from the prep area.

Additional information

- Use with care in premature infants or infants under 2 months of age. These products may cause irritation or chemical burns.
- Discard the applicator after a single use.
- Note that the applicator is latex-free and for external use.
- Use in a well-ventilated area.
- Do not use for lumbar puncture or in contact with the meninges.
- Do not use on open wounds or as a general skin cleanser.
- Do not use on patients with known allergies to CHG or IPA.
- Keep the solution out of the eyes, ears and mouth.
- Store between 15 to 30 °C (59 to 86 °F).
- Avoid freezing and excessive heat above 40 °C. (104 °F). Store within the recommended conditions to maintain the efficacy.

ChloroPrep representative: _____

In-service dates: _____

Time: _____

Reorder #: _____

Location of ChloroPrep applicators at this facility: _____

carefusion.com/chloroprep | 800.523.0502

ChloroPrep®

Patient preoperative skin preparation
2% chlorhexidine gluconate (CHG) and 70% isopropyl alcohol (IPA)

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EXHIBIT I11

ChloroPrep® SEPP® 0.67 mL applicator

Patient preoperative skin preparation
2% chlorhexidine gluconate (CHG) and 70% isopropyl alcohol (IPA)



Application instructions



Pinch

- Hold the applicator as shown with the sponge tip facing down. Do not touch the tip.
- Pinch the applicator **only once** to activate it and release the antiseptic.



Apply

- Allow the solution to partially load in the sponge. Gently press the applicator tip against the treatment area until liquid is visible on the skin.
- Completely wet the treatment area with antiseptic, using gentle back-and-forth strokes, progressing from the insertion/incision site to the periphery:
 - **For dry sites** (e.g., abdomen or arm): Use gentle, repeated back-and-forth strokes for 30 seconds.
 - **For moist sites** (e.g., inguinal fold or axilla): Use gentle, repeated back-and-forth strokes for two minutes.



Dry

- For dry surgical sites, allow the area to dry for approximately 30 seconds.
- For moist surgical sites, allow the area to dry for approximately one minute.
- Do not blot or wipe away the solution.
- The solution must be dry for optimal drape/dressing adhesion.

Before using the ChloroPrep SEPP® 0.67 mL applicator, read the instructions on the package. Use in accordance with the policies and procedures of your hospital.



Catalog number

260449

Approximate coverage area: 2.5" x 2.5"
200 applicators per carton,
10 cartons per case

Important safety points

- **Do not repeatedly pinch or pump the applicator in an attempt to accelerate the saturation of the applicator tip.**

Safety points for products containing alcohol

- Do not use with electrocautery.
- Do not allow the solution to pool.
- Remove wet materials from the prep area.

Additional information

- Use with care in premature infants or infants under 2 months of age. These products may cause irritation or chemical burns.
- Discard the applicator after a single use.
- Note that the applicator is latex-free and for external use.
- Use in a well-ventilated area.
- Do not use for lumbar puncture or in contact with the meninges.
- Do not use on open wounds or as a general skin cleanser.
- Do not use on patients with known allergies to CHG or IPA.
- Keep the solution out of the eyes, ears and mouth.
- Store between 15 to 30 °C (59 to 86 °F).
- Avoid freezing and excessive heat above 40 °C (104 °F). Store within the recommended conditions to maintain the efficacy.

ChloroPrep representative: _____

In-service dates: _____

Time: _____

Reorder #: _____

Location of ChloroPrep applicators at this facility: _____

carefusion.com/chloraprep | 800.523.0502

ChloroPrep®

Patient preoperative skin preparation
2% chlorhexidine gluconate (CHG) and 70% isopropyl alcohol (IPA)

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CareFusion

EXHIBIT I12

ChloroPrep® swabstick applicator

Patient preoperative skin preparation
2% chlorhexidine gluconate (CHG) and 70% isopropyl alcohol (IPA)



Application instructions



Tear

- Tear the pouch at the side notch to reveal the applicator handle.



Apply

- Twist and remove the packaging tip. Do not touch the foam applicator tip.
- Place the foam flat side down on the treatment area.
- Completely wet the treatment area with antiseptic, using gentle back-and-forth strokes, progressing from the insertion/incision site to the periphery:
 - **For dry sites** (e.g., abdomen or arm):
Use gentle, repeated back-and-forth strokes for 30 seconds.
 - **For moist sites** (e.g., inguinal fold or axilla):
Use gentle, repeated back-and-forth strokes for two minutes.



Dry

- For dry surgical sites, allow the area to dry for approximately 30 seconds.
- For moist surgical sites, allow the area to dry for approximately one minute.
- Do not blot or wipe away the solution.
- The solution must be dry for optimal drape/dressing adhesion.

Before using the ChloroPrep® swabstick applicator, read the instructions on the package. Use in accordance with the policies and procedures of your hospital.



Catalog number

260100

Approximate coverage area: 2.5" x 2.5"
48 pouches per carton,
10 cartons per case

Safety points for products containing alcohol

- Do not use with electrocautery.
- Do not allow the solution to pool.
- Remove wet materials from the prep area.

Additional information

- Use with care in premature infants or infants under 2 months of age. These products may cause irritation or chemical burns.
- Discard the applicator after a single use.
- Note that the applicator is latex-free and for external use.
- Use in a well-ventilated area.
- Do not use for lumbar puncture or in contact with the meninges.
- Do not use on open wounds or as a general skin cleanser.
- Do not use on patients with known allergies to CHG or IPA.
- Keep the solution out of the eyes, ears and mouth.
- Store between 15 to 30 °C (59 to 86 °F).
- Avoid freezing and excessive heat above 40 °C (104 °F). Store within the recommended conditions to maintain the efficacy.

ChloroPrep representative: _____

In-service dates: _____

Time: _____

Reorder #: _____

Location of ChloroPrep applicators at this facility: _____

carefusion.com/chloraprep | 800.523.0502

ChloroPrep®

Patient preoperative skin preparation
2% chlorhexidine gluconate (CHG) and 70% isopropyl alcohol (IPA)

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EXHIBIT I13

ECOLAB®

43737

Net Weight: 100 lb/45.4 L

Trichlor-O-Cide® XP-160

Powdered Sanitizer

ACTIVE INGREDIENT:

Sodium dichloro-s-triazinetrione dihydrate.....27.3%

INERT INGREDIENTS:72.7%

TOTAL:100.0%

Provides a minimum of 15% available chlorine

Formula contains no phosphorus.

**KEEP OUT OF REACH OF CHILDREN
DANGER**

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER: CORROSIVE. Causes irreversible eye damage. Causes skin irritation. Harmful if swallowed, inhaled or absorbed through skin. Do not get in eyes, on skin or on clothing. Wear goggles, face shield or safety glasses. Wash thoroughly after handling. Remove contaminated clothing and wash before reuse.

EPA Reg. No. 1677-91

EPA Est. 1677-IL-2 (J), 1677-NJ-1 (W), 1677-TX-1 (D), 1677-GA-1 (M), 1677-CA-1 (S), 1677-MN-1 (P), 1677-PR-1 (B), 11321-CA-1 (C), 1677-OH-1 (H), 1677-CA-2 (R), 303-IN-1 (L), 1677-MO-1 (K), 1677-WV-1 (V), 6574-KY-001.

Superscript refers to first letter of date code.

Ecolab Inc., Food & Beverage Division
370 Wabasha Street N.
St. Paul, Minnesota 55102-1390 U.S.A.

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FIRST AID

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment advice.

IF SWALLOWED: Call a poison control center or doctor for treatment advice. Have a person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

**FOR EMERGENCY MEDICAL INFORMATION IN USA OR CANADA,
CALL: 1-800-328-0026.**

**FOR EMERGENCY MEDICAL INFORMATION WORLDWIDE,
CALL: 1-651-222-5352 (IN THE USA).**

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

PHYSICAL AND CHEMICAL HAZARDS:

Strong oxidizing agent. Do not mix with acids, will cause hazardous vapors. Mix only with water according to label directions. Do not store or use in a manner that would contaminate food or feed.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish and aquatic organisms. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public waters unless in accordance with the requirements of National Pollutant Discharge Elimination System (NPDES) permit and permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

DAIRY, BEVERAGE AND FOOD PROCESSING PLANTS:

Remove gross food particles and soil by a pre-flush or pre-scrape and, when necessary, presoak the surface(s) to be sanitized. Clean utensils and equipment thoroughly with an appropriate detergent and rinse with potable water. Before use, sanitize these items with a 50 to 100 ppm available chlorine (0.5 oz. to 1 oz. per 12 gallons) solution of *Trichlor-O-Cide XP-160* for a two minute exposure period. Use immersion, spray or circulation techniques as appropriate to the equipment. Allow to drain thoroughly and air dry.

NOTE: DO NOT SOAK OVERNIGHT.

DIRECTIONS FOR FOGGING: Prior to fogging, clean all surfaces and remove or carefully protect all food products and packaging materials. Fog desired areas using one quart per 1000 cubic feet of room area with a *Trichlor-O-Cide XP-160* solution containing 600 ppm available chlorine (1 oz to 2 gal). Vacate the area of all personnel for a minimum of 2 hours after fogging. All food contact surfaces must be rinsed with an EPA registered food contact surface sanitizer following fogging. Allow surfaces to drain thoroughly before operations are resumed.

FOGGING IS TO BE USED AS AN ADJUNCT TO ACCEPTABLE MANUAL CLEANING AND DISINFECTING OF ROOM AND MACHINE SURFACES.

NOTE: FOR MECHANICAL OPERATIONS prepared use solution may not be reused for sanitizing but may be reused for other purposes such as cleaning.

FOR MANUAL OPERATIONS fresh sanitizing solutions should be prepared at least daily or more often if the solution becomes diluted or soiled.

FOOD SHELL EGG SANITIZATION

Only clean, whole eggs can be used for sanitizing. Dirty, cooked, or punctured eggs cannot be used. Thoroughly mix 0.5 to 1 oz. of this product with 12 gallons of warm water to provide a 50 to 100 ppm available chlorine solution. The sanitizer temperature should not exceed 130° F. Spray the warm sanitizer so that the eggs are thoroughly wetted. Allow the eggs to thoroughly dry before casing or breaking. Do not apply a potable water rinse. The solution should not be reused to sanitize eggs.

STORAGE & DISPOSAL

DO NOT CONTAMINATE WATER, FOOD OR FEED BY STORAGE OR DISPOSAL.

STORAGE: Product should be stored in a dry location.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL: Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused, dispose of in the same manner.



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EXHIBIT I14

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ChlorCid® and ChlorCid® V

3% Sodium Hypochlorite Solutions



Select One



ChloridCid



ChlorCid V

CERTIFICATE OF SERVICE

I hereby certify that, on this 21st day of May, 2015, a true and correct copy of **APPLICANT'S NOTICE OF RELIANCE** has been served by electronic mail upon Opposer's attorneys of record in this proceeding at the following electronic addresses:

Joseph R. Dreitler, Esq.
Mary R. True, Esq.
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/s/ April R. Morris

April R. Morris