

The Impact of Healthcare Reform (PPACA) On the U.S. IVD Industry

<https://marketpublishers.com/r/I9E4EAA1387EN.html>

Date: August 2013

Pages: 68

Price: US\$ 1,500.00 (Single User License)

ID: I9E4EAA1387EN

Abstracts

The 'Patient Protection and Affordable Care Act' (H.R. 3590) is complex legislation that affects virtually every aspect of health care, and many of its provisions are beginning to take effect now. IVD manufacturers who have different needs and strategies are now considering the legislation and whether it will help or hurt business plans. The legislation contains a range of different provisions and while the law in a broad sense is expected to have a positive result in terms of net sales and procedure volume increases, it will also impose challenges, including cost containment initiatives and reimbursement cuts.

Kalorama has been analyzing IVD markets for decades and brings its knowledge of the market to this new law. This report, examines the effects of the Patient Protection and Affordable Care Act's provisions on IVD sales, procedure volumes and profits. Analyst Alison Sahoo calculates the effects of the legislation good and bad in a way that business planners can utilize.

The overall objective of the PPACA is to expand access to health care coverage for most U.S. citizens and legal residents by requiring individuals to have coverage and employers to either provide coverage or pay a penalty that would support coverage from a pool of public funds. Approximately 46 million American residents had no health care insurance as of early 2010. Under the new law, insurance will be extended to as many as 32 million of these persons through a variety of methods taking effect through 2014. The PPACA utilizes the state-run Medicaid program, which was originally established in 1965 as an entitlement program for low income families and other persons who met eligibility requirements such as persons who are blind, disabled and/or pregnant, as a major vehicle to extend health care coverage. However, it also imposes cost containment requirements on Medicaid as well as Medicare, the federal health care program for persons age 65 and older.

The report examines the proposed positive developments for the IVD industry resulting from PPACA such as an expansion in the number of insured U.S. persons, increased utilization of tests related to nosocomial infections, product innovation resulting from value-based pricing, and new coverage of wellness and prevention programs. The report also examines legislation components that might present challenges, such as the medical device excise tax and changes to Medicare reimbursement. Finally, the report looks at the unresolved questions of the legislation.

In the course of its analysis, the report provides the following:

COMPLETE EXPLANATION OF THE LEGISLATION AND MAJOR PROVISIONS

IMPLEMENTATION OF SELECTED PPACA PROVISIONS BY YEAR

CURRENT STATUS OF PPACA IMPLEMENTATION

U.S. IVD PROCEDURE VOLUMES, 2012-2022

U.S. MARKET FOR IVD AND CLINICAL LAB TESTS, 2012 – 2022

IMPACT OF EXPECTED INCREASE IN NEWLY INSURED PATIENTS

LIKELY NEW SALES DUE TO NOSOCOMIAL INFECTION PROVISIONS

NEW SALES FROM DEVICE INNOVATION DEMAND RESULTING FROM PPACA

ESTIMATED LOSS OF REVENUES FROM TAXES AND MEDICARE CUTS

EFFECT OF WELLNESS AND PREVENTION PROGRAMS

RECENT IVD CONSOLIDATION

THE ROLE OF ACOS

IMPACT OF THE MEDICAL DEVICE TAX AND RECENT DEVELOPMENTS

STATE EXPANSION OF MEDICAID

IVD CAPITAL PURCHASING, PUBLIC CONFUSION AND OTHER TRENDS.

Beginning in January 2014, the PPACA will create Health Benefit Exchanges (HBEs) through which U.S. citizens and legal immigrants who are not incarcerated and small businesses with up to 100 employees can purchase qualified coverage. The PPACA requires the establishment of a Small Business Health Options Program (SHOP exchange) in each state. Beginning in 2017, SHOP will allow small businesses with up to 100 employees to offer either a single plan to all of their workers or select a benefit level and allow employees to choose among several plans offered at that level.

Different aspects of the complex health care reform legislation will affect the IVD industry differently, with some provisions exerting a positive effect to stimulate growth and other provisions exerting a negative effect. Several key provisions of the PPACA, in combination with favorable population demographics, will stimulate IVD product sales. The most significant provision of the PPACA for most health care manufacturers and providers is growth in the number of persons with health care coverage. Offsetting these industry drivers are industry restraints resulting from the PPACA that will act to mitigate against greater expansion of IVD testing. In January 2013, a new excise tax on virtually all medical devices went into effect. In addition to other cost cutting initiatives, the Medicare clinical laboratory fee schedule update factor will be reduced.

In this report, sales estimates for the overall market represent U.S. revenues and are expressed in current dollars. Estimates are provided for the historic 2012 period and forecasts are provided through 2022. The report also presents overall procedure volumes for IVD and laboratory tests. It covers only commercialized tests, specifically excluding those that are developmental or used primarily for research purposes. Historical information for this report was gathered from a wide variety of published sources including company reports and filings, government documents, legal filings, trade journals, newspapers and business press, analysts' reports and other sources.

Contents

CHAPTER ONE: EXECUTIVE SUMMARY

THE IMPACT OF HEALTH CARE REFORM ON THE U.S. IVD INDUSTRY

Scope and Methodology

Health Care Reform

CHAPTER TWO: UNDERSTANDING HEALTH CARE REFORM

OVERVIEW OF KEY LAW COMPONENTS THAT AFFECT THE IVD INDUSTRY

General Provisions

Changes to Public Programs

Medicaid

Medicare

Changes to Private Insurance

Health Benefit Exchanges

Small Business Health Options Program

Accountable Care Organizations

Integrated Delivery Networks

Expanded Access to Primary Care

Prevention and Wellness Initiatives

Long Term Care

Nosocomial Infections

Comparative Effectiveness Research

Medical Device Tax

Other Provisions

Implementation Timetable

Impact on the IVD Industry

IVD Industry Drivers

U.S. Demographics

Nosocomial Infections

Prevention and Wellness Programs

Product Innovation

IVD Industry Restraints

Medical Device Tax

Medicare Payments

Bundled Payments

CHAPTER THREE: THE U.S. IVD MARKET AND IMPACT OF REFORM

OVERVIEW

SALES FORECASTS 2012 2017

- Sales Impact of PPACA Drivers

- Sales Impact of PPACA Restraints

PROCEDURE VOLUME FORECASTS 2012 2017

- Procedure Volume Impact of PPACA Drivers

- Procedure Volume Impact of PPACA Restraints

OTHER EFFECTS OF THE PPACA

- Impact on IVD Profitability

- IVD Industry Consolidation

- Reduction in IVD Capital Equipment Purchasing

- Shift in Health Care Delivery

CHAPTER FOUR: UNRESOLVED HEALTH CARE REFORM ISSUES IMPACTING THE IVD INDUSTRY

OVERVIEW

MEDICAL DEVICE TAX

DIAGNOSTICS PAYMENT REFORM

STATE EXPANSION OF MEDICAID

PUBLIC CONFUSION ABOUT THE PPACA

List Of Exhibits

LIST OF EXHIBITS

CHAPTER TWO: UNDERSTANDING HEALTH CARE REFORM

TABLE

STATUS OF ACTION ON MEDICAID EXPANSION, AUGUST 2013

TABLE

IMPLEMENTATION OF SELECTED PPACA PROVISIONS BY YEAR

TABLE

POPULATION DISTRIBUTION BY AGE, 1990, 2000, 2010 AND 2020

CHAPTER THREE: THE U.S. IVD MARKET AND IMPACT OF REFORM

TABLE

TYPES OF IVD AND CLINICAL LAB TESTS, 2013

TABLE

U.S. SALES OF IVD AND CLINICAL LAB TESTS, 2012 – 2022, IN \$MILLION

TABLE

IMPACT OF PPACA SALES DRIVERS ON U.S. SALES OF IVD AND CLINICAL LAB TESTS, 2012 – 2022

FIGURE

IMPACT OF PPACA SALES DRIVERS ON U.S. SALES OF IVD AND CLINICAL LAB TESTS, 2012 – 2022

TABLE

IMPACT OF PPACA SALES RESTRAINTS ON U.S. SALES OF IVD AND CLINICAL LAB TESTS, 2012 – 2022

FIGURE

IMPACT OF PPACA SALES RESTRAINTS ON U.S. SALES OF IVD AND CLINICAL LAB TESTS, 2012 – 2022

TABLE

U.S. PROCEDURE VOLUME FOR IVD AND CLINICAL LAB TESTS, 2012 – 2022

TABLE

IMPACT OF PPACA DRIVERS ON U.S. PROCEDURE VOLUME FOR IVD AND CLINICAL LAB TESTS, 2012 – 2022

FIGURE

IMPACT OF PPACA DRIVERS ON U.S. PROCEDURE VOLUME OF IVD AND CLINICAL LAB TESTS, 2012 – 2022

About

Small Business Health Options Program

The PPACA requires the establishment of a Small Business Health Options Program (SHOP exchange) in each state. Beginning in 2017, SHOP will allow small businesses with up to 100 employees to offer either a single plan to all of their workers or select a benefit level and allow employees to choose among several plans offered at that level.

Accountable Care Organizations

Under the PPACA, an Accountable Care Organization (ACO) is defined as a group of health care providers who deliver coordinated and chronic disease management to improve the quality of care patients receive while reducing cost. To qualify as an ACO, organizations must agree to be accountable for the overall care of their Medicare beneficiaries, have adequate participation of primary care physicians, define processes to promote evidence-based medicine, report on quality and costs, and coordinate care. This may include various types of groups including:

- physicians and hospitals in group practice;
- networks of individual practices;
- joint ventures between hospitals, providers and commercial payers;
- critical access hospitals, rural health centers and/or federally qualified health centers.

If they meet benchmarks developed by the Centers for Medicare & Medicaid Services (CMS), ACOs may share in cost savings achieved for the care provided. As a result, many major U.S. health insurers including Aetna, Humana and WellPoint are retooling to become more than just health plans. This includes diversification plan and acquisitions and partnerships that allow the companies to employ doctors directly, deliver health-information technologies, and participate in new hospital-doctor group ACOs. As of mid 2013, about 300 ACOs operated across the U.S. The impact on the IVD industry will be buyers with more economies of scale and a rationalization of test usage to limit repeats and redundancies.

I would like to order

Product name: The Impact of Healthcare Reform (PPACA) On the U.S. IVD Industry

Product link: <https://marketpublishers.com/r/I9E4EAA1387EN.html>

Price: US\$ 1,500.00 (Single User License / Electronic Delivery)

If you want to order Corporate License or Hard Copy, please, contact our Customer Service:

info@marketpublishers.com

Payment

To pay by Credit Card (Visa, MasterCard, American Express, PayPal), please, click button on product page <https://marketpublishers.com/r/I9E4EAA1387EN.html>

To pay by Wire Transfer, please, fill in your contact details in the form below:

First name:
Last name:
Email:
Company:
Address:
City:
Zip code:
Country:
Tel:
Fax:
Your message:

****All fields are required**

Customer signature _____

Please, note that by ordering from marketpublishers.com you are agreeing to our Terms & Conditions at <https://marketpublishers.com/docs/terms.html>

To place an order via fax simply print this form, fill in the information below and fax the completed form to +44 20 7900 3970