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

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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.

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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

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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.

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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.

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