Supporting Statement – Part A

Supporting Statement For Paperwork Reduction Act Submissions

A. Background

The Predictive Learning Analytics Tracking Outcome (PLATO™) is a web-based application tool that will serve as the centerpiece of the advanced analytics initiative with the Centers for Medicare & Medicaid Services (CMS) and Health Integrity, LLC, the National Benefit Integrity Medicare Integrity Contractor (NBI MEDIC). Developed by Health Integrity, LLC and licensed for one of its contracts—the NBI MEDIC—PLATO™ utilizes a cutting-edge advanced analytics fraud detection process in conjunction with a state-of-the-art web-based user interface tool to present fraud and abuse lead information visually to Medicare Part D plan sponsors. Summary data, based on National Prescription Drug Event Data and actions from all Part D plan sponsors, is shared with law enforcement, CMS, NBI MEDIC, and Part D plan sponsors to review historic actions taken against providers who are enrolled in the Medicare Part D program, which will assist in detecting and preventing fraud, waste, and abuse.

B. Justification

1. Need and Legal Basis

CMS has a need to better identify drug diversion and enhance the detection and prevention of fraud, waste and abuse in the Medicare Part D program. In order to ensure the protection of the Medicare Trust Fund, CMS contracts and works with the NBI MEDIC to support CMS' audit, oversight and antifraud and abuse efforts associated with the Medicare Advantage (MA /Part C) and Prescription Drug (Part D) programs. The program integrity provisions throughout the Affordable Care Act of 2010 (ACA), and particularly in Title VI, outline expectations for proactive detection and prevention of fraud, waste, and abuse, as well as robust program management, performance measurement, and reporting.

Title I of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) (P.L. 108-173) was signed into law on December 8, 2003. The MMA established a new voluntary outpatient prescription drug benefit under Part D of Title XVIII of the Social Security Act (the Act). The prescription drug benefit, referred to as Medicare Part D, as well as an employer subsidy for qualified retiree health plans, began on January 1, 2006. Coverage for the drug benefit will be provided by private prescription drug plans (PDPs) that offer drug-only coverage or through Medicare Advantage (MA) plans that offer both prescription drug and health care coverage (known as MA-PD plans). It may also be offered by managed care organizations with cost plan contracts under section 1876 of the Act. In

addition, *42 CFR §*423.859 of the final rule states that "each Part D eligible individual must have available a choice of enrollment in at least two qualifying plans." Furthermore, at least one of the two qualifying plans must be a prescription drug plan. If this requirement is not met, CMS will contract with fallback prescription drug plans (as defined in *42 CFR §*423.855 of the final rule) to provide such access. We refer to all of these plans in general as "Part D plans." These plans must offer a standard drug benefit, but will have the flexibility to vary the drug benefit within certain parameters.

The final rule implementing the new Medicare Prescription Drug Benefit and the final rule establishing and regulating the Medicare Advantage (MA) program were published in the Federal Register on Friday, January 28, 2005. A copy of the final regulations is available from the Federal Register online database at https://www.federalregister.gov.

The Patient Protection and Affordable Care Act (P.L. 111-148) was enacted on March 23, 2010. The Health Care and Education Reconciliation Act (P.L. 111-152) was enacted on March 30, 2010 and modified a number of Medicare provisions in P.L. 111-148 and added several new provisions. The Patient Protection and Affordable Care Act (P.L. 111-148) and the Health Care and Education Reconciliation Act (P.L. 111-152) are collectively referred to as the Affordable Care Act of 2010 (ACA). The ACA includes significant reforms of the private health insurance industry as well as the Medicare and Medicaid programs. The ACA strengthens program integrity efforts across Medicare, including Part C (Medicare Advantage) and Part D (Prescription Drug) programs.

2. Information Users

    This is a new collection. CMS, NBI MEDIC, Medicare Part D plan sponsors, and law enforcement will be able to review national summary data and actions taken against Part D providers. This will enable them to detect which providers are most at risk for Medicare Part D fraud, waste, and abuse in order to take the proper actions against the identified Part D providers.

3. Use of Information Technology

    The use of PLATO™ is 100% electronic, as the site for collecting the data is web-based.

    *To comply with the Government Paperwork Elimination Act (GPEA), you must also include the following information in this section:
       - Is this collection currently available for completion electronically?
       Yes, all information is electronic.
       - Does this collection require a signature from the respondent(s)?
       No, a signature is not required from the respondents.
       - If CMS had the capability of accepting electronic signature(s), could this collection be

made available electronically?

> Yes, this collection could be made available electronically.

> - If this collection isn't currently electronic but will be made electronic in the future,
please give a date (month & year) as to when this will be available electronically and explain why
it can't be done sooner.

> Not applicable. The collection tool is entirely electronic.

> - If this collection cannot be made electronic or if it isn't cost beneficial to make it
electronic, please explain.

> Not applicable. The collection tool is entirely electronic.

4. Duplication of Efforts

    This information collection does not duplicate any other effort and the information cannot be
    obtained from any other source.

5. Small Businesses

    There is no impact expected for small businesses as PLATO™ provides the smaller healthcare
    companies with data that they would otherwise have to search for themselves. PLATO™
    provides them with easier and quicker access to information, thus, making this a more
    valuable tool for small businesses and entities to utilize.

6. Less Frequent Collection
    This data collection is to aid in the more efficient identification, prediction, and prevention of
    Medicare Part D fraud, waste, and abuse. Without this tool, Medicare Part D plan sponsors
    will not be given the advantage of national summary data to aid them in detecting fraudulent
    providers and actions in a much more efficient and effective manner.

7. Special Circumstances

    There are no special circumstances associated with this information collection request.

8. Federal Register/Outside Consultation

    The 60-day *Federal Register* notice published on April 25, 2014.

9. Payments/Gifts to Respondents

    No payment or gifts to respondents. The information provided is complimentary to Part D
    plan sponsors and law enforcement.

10. Confidentiality

   PLATO™ only allows two users per Medicare Part D plan sponsor contract to access the data. Although all national summary data is shared, Part D plan sponsor users that are not within the same contract are not able to see personal identifiers of who took the action against the Part D provider, but are only able to see what action was taken, the allegation type, the date of action, and error percentage. Users within the same contract will be able to view all action details such as: the username, organization name, and contract identifier as well as the action taken, allegation type, date of the action, and error percentage.

11. Sensitive Questions

   Not applicable. No questions of a sensitive nature will be asked of respondents.

12. Burden Estimates (Hours & Wages)

   We plan to release the application to the entire Medicare Part D plan sponsor community, which to date, would be 775 plan contracts, making it 1,550 users for the system. It is estimated that each plan sponsor user will access the PLATO™ application for 1 hour each month (12 annual burden hours per user). By multiplying the 1,550 Part D plan sponsor system users by 12 hours, will result in 18,600 total annual burden hours collectively. Depending on the users' searching needs, they may spend anywhere from 10 seconds to 10 minutes searching and investigating Medicare Part D providers that they are enrolling or who are already within their network.

   The estimated time for a Compliance Officer working for a Part D plan sponsor is at least one hour a month to search and review potential and existing Part D providers for fraud, waste and abuse. According to the Bureau of Labor Statistics, a Compliance Officer makes a national average of $60,740 annually and thus $29.20 an hour by dividing $60,740 by 2,080 work hours per year. One hour is estimated for the time spent for each user a month, and there will be two users per Part D plan sponsor contract. The hourly rate of $29.20 multiplied by two users, amounts to $58.40 a month to Part D plan sponsors for the cost of two users. Multiplying the cost of two users a month of $58.40 by 12 annual hours for each response will total $700.80 annually for PLATO™ usage for each Part D plan sponsor contract.

13. Capital Costs

   There are no foreseen capital costs to respondents as they are not requested to record or store information that is collected. PLATO™ is a free web-based tool for Part D plan sponsors and law enforcement to utilize and will not be required to spend any extra amount of money. The Part D plan sponsors will already possess the necessary equipment, such as computer and Internet access, to provide and search information in PLATO™. This will give them the

advantage of obtaining national data without any capital costs to them.

14. Cost to Federal Government

Health Integrity's salary policy is to develop salary ranges that are relatively competitive in the marketplace. As a result, almost every position will be placed into a salary range based on an established market rate of reported salaries for comparable positions within the relevant job. Our target market rate is the 50th percentile. On a selected basis and with the CEO's approval, key positions, due to the nature of the market and the importance of those positions in our business strategy, may be placed at a more competitive rate to ensure that Health Integrity is able to lead the market in recruiting and retaining individuals in these key positions.

Our staffing level assumptions are based on Health Integrity's historical knowledge performing the same type of work on the PLATO™ solution. This includes full time equivalents (FTE's) for Data Modelers to create the predictive models; IT Developers to configure and customize the PLATO™ system; a Statistician who will confirm the statistical validity of the predictive modeling methodology; a Project Manager to manage the daily operations of the project; and a Trainer who will develop training materials and train the users.

Indirect costs were estimated at the FY2015 Health Integrity budgeted rates for leave, fringe, overhead, and general & administrative costs. Other direct costs (ODC) such as facility costs, telephone/teleconferences, and reproduction/printing costs are estimated based on Health Integrity's historical ODC costs on other similar contracts.

Total Labor, Leave, and Fringe	$ 545,036.25
Total Non-Labor Costs	$ 886,770.93
Total Cost	$1,431,807.18

We feel certain that PLATO™ will greatly enhance the oversight and operations of the Medicare Part D program. PLATO™ utilizes a real-time predictive modeling fraud detection process in conjunction with a state of the art web-based user interface tool, which, when implemented, will greatly increase the likelihood of identifying fraud, minimize false positives, and provide in a more efficient timeframe real-time reporting capabilities on outcomes to CMS and the U.S. Senate.

PLATO™ builds on proven algorithms by using attributes and outcomes from both rule-based analysis (related attributes of pharmacies, prescribers, beneficiaries) and advanced analytics (e.g., logistic regression, decision trees, artificial intelligence, support vector machine), along with

patterns discernible from non-traditional data (e.g., public records of wrongdoing, business relationships among the parties involved in the prescriptions, and social media information about the companies and individuals).

Health Integrity is aware of the continuing attention the Medicare Part D program receives from internal departmental and external oversight groups, both legislative and administrative. PLATO™ will provide CMS with a set of advanced analytic approaches and related outcomes that will assist CMS in responding to these oversight groups.

15. Changes to Burden

Explain the reasons for any changes to the burden (hours and/or capital costs). Explain whether this is due to a program change or adjustment. This is in reference to number 13 and/or 14 of the OMB Form 83-I.

Not applicable. No changes being implemented to an existing burden.

16. Publication/Tabulation Dates

Not applicable. No information will be published.

17. Expiration Date

CMS does not have any objection to displaying the expiration date. The PLATO™ application website will display the OMB approval number and the expiration date for the OMB approval.

18. Certification Statement

Not applicable.