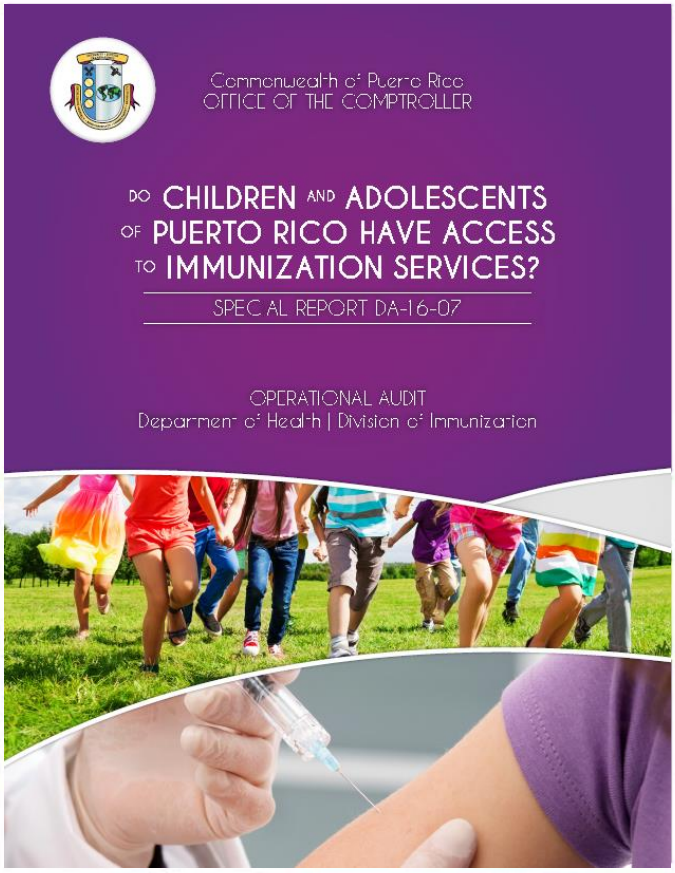
Commonwealth of Puerto Rico
OFFICE OF THE COMPTROLLER

DO CHILDREN AND ADOLESCENTS OF PUERTO RICO HAVE ACCESS TO IMMUNIZATION SERVICES?

SPECIAL REPORT DA-16-07

OPERATIONAL AUDIT
Department of Health | Division of Immunization



SPECIAL REPORT

DA-16-07

November 3, 2015

Operational Audit:

Department of Health
Division of Immunization

Unit:

2235

Audit:

13904

Period Audited:

January 1, 2011 -
February 28, 2015

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Commonwealth of Puerto Rico

OFFICE OF THE COMPTROLLER

San Juan, Puerto Rico

November 3, 2015

To the Governor, and to the presidents of the Senate
and of the House of Representatives

We performed an operational audit of the Division of Immunization of the Department of Health (Department), in order to determine if the division performed effectively, efficiently and economically in the discharge of its functions, and in pursuit of its goals and objectives. An additional purpose of the audit was to evaluate the accessibility of immunization services in Puerto Rico for children below the age of 18 years. We conducted the audit pursuant to the powers granted us by Article III, Section 22 of the Constitution of the Commonwealth of Puerto Rico, and by *Public Law No. 9 enacted on July 24, 1952*, as amended.

WHAT IS AN OPERATIONAL AUDIT?

An operational audit is the professional, objective, and systematic examination of all or part of the operations of an entity, project, program, the units comprising it and specific operations. This type of audit is done so as to determine the degree of effectiveness, economy and efficiency of the operations audited, in order to formulate recommendations with the goal of improving those activities, and to produce a report on the operations evaluated.

HOW WAS THE OPERATIONAL AUDIT CONDUCTED?

We conducted the examination in accordance with the auditing standards of the Comptroller of Puerto Rico in terms of the aspects of performance or execution.

We performed the tests we considered necessary, based on sampling and according to the circumstances, such as: interviews with officials, employees and parties related to the objective of the audit; physical inspections; examination and analysis of reports and of documents produced by the unit audited and by external sources; tests and analysis of financial information, internal control procedures, from the results of a survey on the immunization taken from physicians, and from other pertinent information.

Additionally, we formed a **Reference Panel** with experts on diverse subjects related to statistics, health and public administration for purposes of obtaining specialized and independent opinions on our audit. **APPENDIX 1** contains a detail of the members of that Panel.

The operational audit covered the period from itinerary January 1, 2011 - February 28, 2015. For some aspects we examined results and operations from earlier and later dates.

HOW WAS THE OPERATIONAL AUDIT EVALUATED AND WHAT WAS THE RESULT?

In this operational audit we evaluated access to immunization services for children and adolescents below the age of 18 in Puerto Rico; the structure of the accountability system (performance system) of the Department's Division of Immunization and operational performance under that system; and the principle of economy in the execution of the federal *Vaccines for Children* (*VFC* Program). We determined 4 results and 6 observations.

DEFINITIONS

Public Beneficiary - a person who is a beneficiary of the Health Plan of the Government of Puerto Rico (Plan Mi Salud [My Health Plan] and who qualifies for *Medicaid*.

330 Centers - private non-profit organizations that receive federal funds under Section 330 of the *Public Health Service Act*, for providing services in areas with limited access to healthcare.

Copayment - a concept used in private medicine to define the difference between the price of a service and the amount covered by health

insurance. Thus, this concerns the amount the affiliate must pay in order to access such service.

Economy - principle measuring whether costs are kept low and if the funds used by the audited entity for its activities are available on time, in the appropriate amounts and quality, and at the best possible price.

Effectiveness - principle measuring the achievement of specific goals, established objectives and expected outcomes.

Efficacy - principle measuring the achievement of objectives and the desired impact, and their relation to the resources allocated.

Efficiency - principle measuring whether or not the best possible use was made of available resources. This has to do with the best possible relation between resources employed, existing conditions and the results obtained in terms of quantity, quality and opportunity of the results or achievements.

Healthy People 2020 - objectives for measuring the health of American citizens by 2020 established by an interagency group in collaboration with the Federal Department of Health and other federal agencies.

Performance Indicator - expresses the attainment of a goal in quantitative terms for each performance target. These are the most specific results that must be achieved in the shorter term in order for objectives to be met. This measure is, in quantifiable form, what must be obtained in order to meet the goal. This is established for each goal.[1]

Immunization - administration tech definition into the human body of a vaccine or toxoid by injection or oral administration in order to remain protected from certain diseases.[2]

Performance Goal - means the achievements expected during the fiscal year covered by the Annual Work or Execution Plan for each Strategic Objective. The expression of the achievement includes the date on which it will be attained, and is drafted such that its attainment can be

[1] According to the manual *Definition of Terms for the Preparation of Strategic Plans and Annual Plans*, December 2011 (Revised January 2013), provided by the Office of Management and Budget.
[2] According to Law No. 25 Enacted on September 23, 1983.

confirmed. It is the primary goal to be achieved according to programmatic commitments.[3]

Strategic Goal - statements of outcomes that describe the achievements, effects or consequences expected as a result of the implementation of more than one strategy over a relatively long period of time, generally more than one year. A Strategic Goal states the expected outcome and when it will be met. It is stated in such a way that it helps to assess whether or not the result was attained.[3]

Metric - used to present the progress or end of an activity in the annual plan. Consists of a report or number; the number indicates the goal that will be met.[3]

Strategic Objective - represents the agency's thinking in terms of the safest, most effective and efficient way to achieve strategic goals. Requires considering diverse strategic options and taking into account fiscal considerations, human resources, current legislation and regulations, collective-bargaining agreements, organizational structure, facilities and equipment, values, motivation and communication. This is the expression of the goals we wish to achieve in the long term.[3]

Health Insurance Organization or Insurer - entity subject to insurance laws and regulations under the jurisdiction of the Insurance Commissioner that contracts or offers to contract for provision, administration, processing or payment of the costs of healthcare services or to reimburse the same, including any for profit or nonprofit corporations for hospital and health services, health services organizations or other entities providing health benefits, services or care plans.[4]

Patient with Limited Coverage - a person whose private medical insurance fails to cover all or part of the immunization service.

Private Patient - a person who has private health insurance.

[3] See footnote 1.
[4] According to Puerto Rico Insurance Code.

Annual Execution Plan or Annual Work Plan - document in which management establishes the objectives to be achieved each year and the means of reaching them. This plan must be in harmony with what is established in the Strategic Plan[5].

Strategic Plan - document in which management lays out what its strategy will be for a given period. The plan must be quantitative, as it describes how to reach goals and the strategies to be followed. It should also be temporal, since it indicates the deadlines the agency has for meeting those goals.[5]

Health Plan - insurance contract, policy, certificate or subscription contract with a health insurance organization, health services organization or any other insurer, provided in consideration or in exchange for the payment of a premium, or on a prepaid basis through which the health insurance organization, health services organization or other insurer is required to provide or pay for the provision of determined medical or hospital services, major medical expenses, dental services, mental health services or services incidental to their provision.[6]

Grandfathered Medical Plan or Protected Plan - a group medical plan which was created, or an individual medical insurance policy that was purchased, on or before March 23, 2010. These are exempt from many of the changes required by the Patient Protection and Affordable Care Act (PPACA), Public Law 111-148 enacted on March 23, 2010. Plans or policies may lose this protected plan status if they make certain significant changes reducing benefits or increasing consumer prices.

Provider - a medical professional who administers immunization services.

General Population - every person residing in Puerto Rico, including people with public insurance, private insurance, and the uninsured.

[5] See footnote 1.
[6] See footnote 4.

Healthcare Services - preventive immunization or vaccination service.[7]

Accountability or Performance System - structure covering the preparation, implementation, evaluation, presentation and publication of the Strategic Plan, the Annual Execution Plan and the Results Report for each agency so as to foster efficacy and efficiency in operations and for government transparency.[8]

Immunization System - group of public and private entities that must provide and oversee immunization services for children and adolescents below the age of 18 in Puerto Rico.

Vaccine - suspension of live, deactivated or dead microorganisms, fractions thereof or protein particles that, when administered, induce an immune response that prevents a disease.[9]

SUMMARY OF RESULTS

The most relevant results related to the Division of Immunization's operational audit are:

1. The Immunization System is effective at providing access to immunization services for children and adolescents who are public beneficiaries.
2. The Immunization System is not effective at providing access to immunization services for private patients under 18 years of age.
3. Private patients are affected by insufficient participation by pediatricians in the provision of immunization services.
4. There is noncompliance by private insurers with recommended immunization services coverage, with no copayment, as required by *Public Law 194–2011, Health Insurance Code of Puerto Rico*, which affects private patients.
5. The Division of Immunization has not been effective in promoting the participation of private providers in immunization.

[7] See footnote 1.
[8] According to ISSAI 20, *Principles of Transparency and Accountability* issued by the International Organization of Supreme Audit Institutions (INTOSAI), on the concept of accountability.
[9] According to Regulation 7902, *To Regulate the Operation of Drug Manufacturing, Distribution and Dispensation Establishments*. Approved August 2, 2010 by the Secretary of Health.

6. As of December 2014, there were 17 municipalities (22%) that had no providers to attend private patients. These are: Ceiba, Ciales, Culebra, Florida, Guánica, Hormigueros, Lajas, Las Marías, Maricao, Maunabo, Morovis, Peñuelas, Rincón, Salinas, Santa Isabel, Vieques and Villalba.
7. The Division of Immunization has not been effective in the oversight of compliance by private providers, schools and other centers with the recording of immunization information in the *Puerto Rico Immunization Registry (PRIR).*
8. The Division of Immunization's Performance System is not effective, because it does not contain the elements needed to measure its activities, objectives and goals.
9. The Division of Immunization complies with the principle of economy in the execution of the *VFC* Program.
10. The lack of quantifiable indicators and goals did not allow our auditors to evaluate the efficacy and efficiency of the division of immunization's execution.

INFORMATION REGARDING THE AUDITED UNIT

The department's Division of Immunization is under the Deputy Secretary of Integrated Family and Health Services. The Division was created to address the responsibility granted the Department by

Public Law No. 25 enacted on September 23, 1983[10] (*Public Law No. 25*) to immunize the population against preventable disease by immunization established by the Secretary of Health. This *Act* establishes that for a child or adolescent to gain admission to a school or preschool, day care or social treatment center, an immunization certificate must be presented. The Secretary of Health annually adopts the immunization itinerary for different ages, which has been consistent with the recommendations of the Centers for Disease Control (CDC)'s Advisory Committee on Immunization Practices (ACIP)[11].

[10] This Law repealed *Public Law No. 234* enacted on July 23, 1974, which was promulgated for purposes of establishing a mechanism so that every minor entering school would be duly immunized against diseases that might interfere with the maximum development of their physical and intellectual capacities.
[11] The CDC is under the Federal Department of Health And Human Services.

As part of the Division of Immunization, the Immunization Program was established, which administers and supervises federal funds received for these purposes. Among the federal funds administered are 317 Funds and *VFC* Program funds.

317 Funds are for mass immunization and for uninsured adults or those who have limited coverage under their insurance plans.

VFC Program funds are for providing vaccinations to children and adolescents under 18 years of age, eligible for Plan Mi Salud [My Health Plan], who have no insurance or whose insurance has limited coverage.

These funds are intended for both the purchase of vaccine and for administration of the immunization program.

Funds for the purchase of vaccines are not transferred directly to the Department. Vaccines are requested from the CDC through an established mechanism for requisitions, and the CDC in turn makes payment for the vaccines to providers. Funds for the administration of the immunization program are managed by the department.

Until 2012, these funds were received through approval of grants, in which the Department had to prepare a plan to comply with program objectives, which was to include annual objectives for each component of the program based on CDC guidelines, the methods of operation, including specific actions to meet each objective; a detailed budget and evidence justifying each component; a detail of the needs for each vaccine; and a detail of the needs and source of the funds.

Since 2013, the funds have been distributed through cooperative agreements through which the Government of Puerto Rico, through the Department, issues a request which indicates: the need for assistance; the objectives of the state; how the funds are to be used; a system for evaluation which will allow for measurement of the level of immunization in public and private educational institutions, and in childcare institutions; and a budget with the corresponding documentation.

Grant proposals from 2008 to 2012 and in the cooperative agreements from 2013 to 2018, establish therein that the responsibilities of the immunization program are to supervise compliance with the regulations established for the use and administration of vaccines acquired with the federal funds assigned, and to direct efforts to increase immunization coverage in Puerto Rico.

Administrative Order No. 240, approved on September 4, 2008 by the Secretary of Health, established that the Department, through its division of immunization, is responsible for establishing the public policy for immunization which will be applied to the population. In order to achieve this objective, it is established that the Division shall provide the vaccines to primary care physicians, who will *VFC* Program providers; maintain the immunization Registry and monitor national immunization coverage; supervise compliance with immunization standards; and maintain immunization statistics and make them available to the public. Further, it is established that it must monitor and report on the adverse effects of the various vaccines.

The immunization registry is a tool recommended and required by several healthcare related entities, among these, the World Health Organization and the CDC. The World Health Organization, in addition to recommending immunization to protect the population and to eradicate a series of preventable diseases by immunization[12], recommends maintaining a registry or reliable statistics of immunization levels in Puerto Rico in order to establish an adequate and efficient immunization system.

The CDC requires state programs and their providers to keep a registry of vaccines administered which establishes the quantities dispensed and their inventories. To do this, the Immunization Program uses the *Puerto Rico Immunization Registry (PRIR)*. Through *Administrative*

[12] Diphtheria, Haemophilus Influenzae, Influenza, Influenza Type B, Hepatitis A and B, Measles, Meningococcal Disease, Mumps, Pertussis, Pneumococcal Disease, Polio, Tetanus, Rubella, Rotavirus, Varicella and Human Papilloma Virus.

Order No. 262 enacted on July 18, 2009, the Department extended this requirement to all healthcare professionals who administer vaccines.

Public Law No. 25 establishes that the schools (public and private) and preschools, day care and social treatment centers, must submit a report to the department indicating the number of students admitted, the number exempted from immunizations (may be for religious or clinical reasons) and the number admitted provisionally. The department determined that those schools and centers must utilize the *PRIR* as the tool for submitting that information.

Law 194-2011, *Health Insurance Code of Puerto Rico*, establishes the criteria regulating health insurance. This forms part of *Insurance Code of Puerto Rico* approved by *Public Law No.* 77 enacted on June 19, 1957, as amended. This was created, among other matters, to establish that all insurers or insurance organizations providing health insurance must, at least, provide coverage with no copayments for the immunizations recommended by the ACIP and by the Department's Advisory Committee on Immunization Practices[13].

Additionally, Public Law 194-2011 establishes that the Secretary of Health must monitor the quality of healthcare services to the public, and the Insurance Commissioner must ensure compliance with those aspects regulated by the same. The Insurance Commissioner must verify that health insurers comply with provision of the required immunization services with no copayments.[14]

The Immunization System is composed of the public and private sectors. The public sector includes the CDC, the division of immunization, *VFC* providers, Esteban Calderón Clinics[15], 330 Centers

[13] Grandfathered or protected plans are excluded from this requirement, pursuant to Regulatory Letter No. 2011-132-AV issued by the Insurance Commissioner on October 26, 2011.

[14] Two health insurance plans in Puerto Rico and health services provided by an employer to its employees through self-insured programs are not subject to the jurisdiction of the Office of the Insurance Commissioner of Puerto Rico, (OCS for its Spanish initials) because they are not considered to be insurers, according to Insurance Code of Puerto Rico.

[15] Centers established by the Department in places where it was difficult for the public and private population to access immunization services.

and Plan Mi Salud [My Health Plan]. The private sector includes physicians, pharmacists, hospitals, clinics and health service insurers. Additionally, as we mentioned, the OCS, the Department of Education (*PRIR* in the schools) and the Department of the Family (*PRIR* in preschool and daycare centers) hold responsibilities within that System.

Private educational and daycare systems are also responsible for verifying the immunization status of children they will admit and the immunization Registry and the *PRIR*.

The budget assigned to the Division of Immunization comes from state and federal funds. For fiscal years 2010-11 and 2012-13, the Division received state funds of $534,818, $734,229 and $1,466,200, respectively; and federal funds of $68,474,260, $67,279,151 and $52,512,772, respectively. Of those federal funds, funds assigned for the acquisition of vaccines under the *VFC* Program were $61,815,000 $853,000, $61,229,420 and $47,476,532 for those years.

APPENDIX 2 contains a detail of the key officials who served during the audited period.

The Department has a website, which may be accessed at the following address: www.salud.gov.pr. This site provides information on the services provided by that entity.

WHO DID WE SHARE THE RESULTS WITH?

The **results** of this *Report* were sent to the Hon. Ana C. Ríus Armendáriz, Secretary of Health, by letters from our auditors dated January 29, and February 20 and 26, 2015. Included with those letters were attachments with details on the **results** in question.

By letters dated February 24 and March 13, 2015, the Secretary of Health answered the correspondence from our auditors. Her comments were considered when writing the draft of this Report.

The draft of the **results** of this *Report* was sent for comment to the Secretary of Health; to the Hon. Rafael Roman Melendez, Secretary of Education; to the Hon. Idalia Colón Rolón, Secretary of the Family; to CPA Luis F. Cruz Batista, Executive Director of the Office Of Management

and Budget (OMB); to Dr. Olga I. Bernardy Aponte, Administrator of the Administration for Childcare and the Integrated Development of Childhood (ACUDEN for its Spanish initials); to Ms. Angela Weyne Roig, Insurance Commissioner; to Prof. David Báez Dávila, Executive Director of the Puerto Rico Council on Education; and to Dr. Francisco Joglar Pesquera, ex-Secretary of Health; by letters dated June 4, 2015.

By letter on June 18, 2015, Dr. Angel M. Rivera Garcia, Director of the Division of Immunization, on behalf of the Secretary of Health, requested an extension which was granted until July 3. On July to the Secretary of Health answered the draft of the **results**.

On June 16, 2015, the Secretary of the Family requested an extension which was granted until July 3. On July 3 the Secretary of the Family answered the draft of the **results**. She indicated, among other things, that she was endorsing the comments made by the Administrator of ACUDEN.

By letter dated June 19, 2015, the Executive Director of the OMB requested an extension which was granted until July 3. On July 3 the Executive Director of the OMB answered the draft of the **results**.

By letter dated June 19, 2015, the Administrator of the ACUDEN requested an extension which was granted until July 3. On July 3 the Administrator of the ACUDEN answered the draft of the **results**.

On June 22, 2015 the Insurance Commissioner answered the draft of the **results**.

On July 2, 2015 the Executive Director of the Education Council of Puerto Rico answered the draft of the **results**.

By letter dated June 29, 2015, on behalf of the Secretary of Education, Mr. Jesus M. Santiago Laboy, ENLACE Official, requested an extension which was granted until July 3. The Secretary of Education entered the draft of the **results** of this *Report* by letter dated July 2, 2015, received by this office on July 21.

All comments submitted were considered in the final draft of this *Report*, and some of these are included in the **results** and **observations**.

On June 24 we sent a follow-up letter to the ex-Secretary of Health; however, he did not answer the draft of the **results** of this report which was sent to him for comment.

WHAT WERE THE RESULTS?

Result 1 - Access to immunization services for children and adolescents below age 18 in Puerto Rico

Our examination of access to immunization services revealed that:

Puerto Rico's Immunization System is effective at providing access to immunization services for children and adolescents who are public beneficiaries

On the other hand, our examination revealed that:

Puerto Rico's Immunization System is not effective at providing access to vaccination services for patients age 17 or younger.

Private patients 18 years of age are given greater access, because they can obtain immunization services through a pharmacist.

Data from the Puerto Rico chapter of the American Academy of Pediatrics (AAP), indicate that in 2014 only 10% of pediatricians provided such services.[16]

Private patients are affected by insufficient pediatrician participation in the provision of immunization services.

We conducted a survey of physicians in Puerto Rico, which was sent electronically on August 12, 2014 through the Puerto Rico Medical Surgeons Association and the AAP to determine if they provide immunization services, the reasons for which they do not provide the services, the availability of providers and municipalities, whether or not

[16] According to information presented in the preamble to Public Law 95 – 2014, *Pharmacy Act*.

they record the information required by the *PRIR*, and the recommendations for providing immunization services and to improve recording in the *PRIR* registry, among others. In spite of the efforts made with the healthcare professional organizations, there was limited participation in our survey by the medical establishment. Only 312 (3%) of the 10,900 professionals belonging to the Medical Association completed the survey. Moreover, only 86 (9%) of the 997 pediatricians belonging to the Association participated.[17]

33% of pediatricians surveyed provide immunization services.

Among the physicians of all specialties answering the survey, 76 (24%) indicated that they provide immunization services. Additionally, 28 (33%) of pediatricians participating in the survey indicated that they provide the services.

The fact that only 33% of pediatricians offer immunization services reflects low participation by this sector. In an article published on March 6, 2008 in the local press, it was noted that, as of that date, of the 1,011 pediatricians on the Island, only 60 (6%) vaccinated. The problem of access to immunization services for private patients has remained the same for the past 7 years.

90% of pediatricians in the U.S. provide immunization services.

According to AAP data, in 2014, almost 90% of pediatricians in the United States provided immunization services. We recommend that similar participation be reached in Puerto Rico.[18]

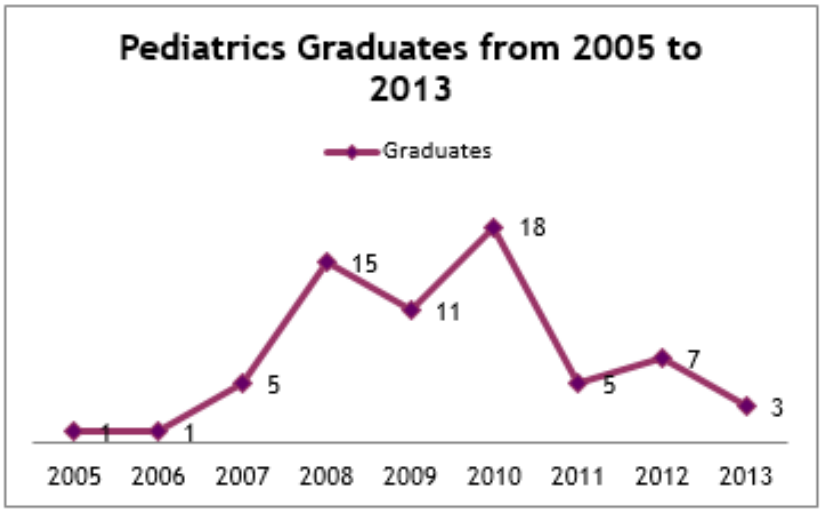
The AAP recommends the primary care model known as the *Medical Home* which involves the provision of immunization services by the patient's pediatrician so that the pediatrician can provide follow-up and so that any conditions that might affect the child's health can be identified and treated in time.[19]. This is because when the patient is taken to an immunization center or to another physician not specialized

[17] According to data from the Puerto Rico Physician Licensing and Discipline Board (Licensing Board), as of September 2014, there were 1,033 licensed pediatricians. Of these, 36 were non-members. In order to exercise medicine in Puerto Rico they must be active members of the Medical Association.
[18] See footnote 16.
[19] *The Medical Home* published in the AAP's *Pediatrics* on July 1, 2002. See http://pediatrics.aappublications.org/content/110/1/184.full.ht.

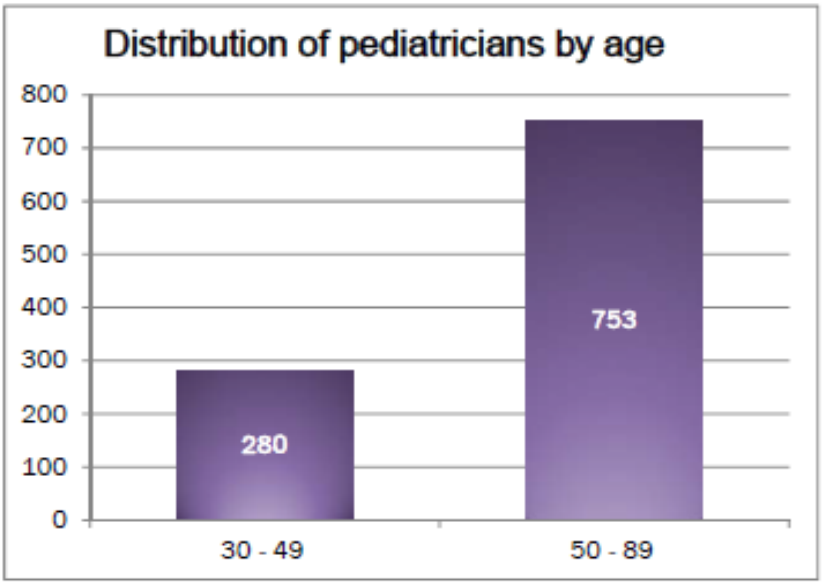
in pediatrics, just to obtain the immunization service, there is no history of the progress or medical conditions which should be followed up on.

The number of pediatricians in Puerto Rico may decrease in the coming decades if adequate measures are not taken. Due to the small number of pediatricians graduating annually and the low rates of immigration of these professionals to Puerto Rico, we will not be able to replace the number that will cease to provide services.

According to data from the Licensing Board the number of health professionals graduating in pediatrics in recent years was as follows:



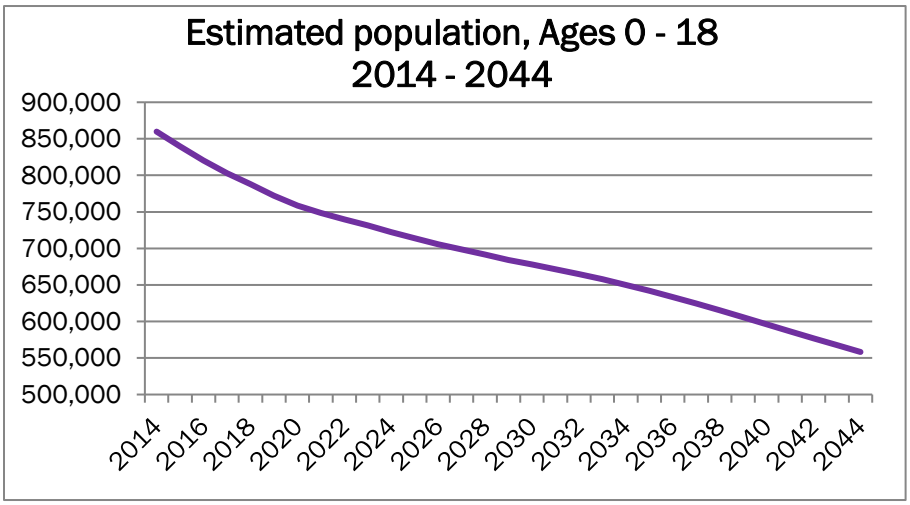
73% of pediatricians are over 50 years of age:



This age distribution should be compared with the average of students graduating. We should also know the estimated number of people below age 18 in Puerto Rico for the next 30 years.

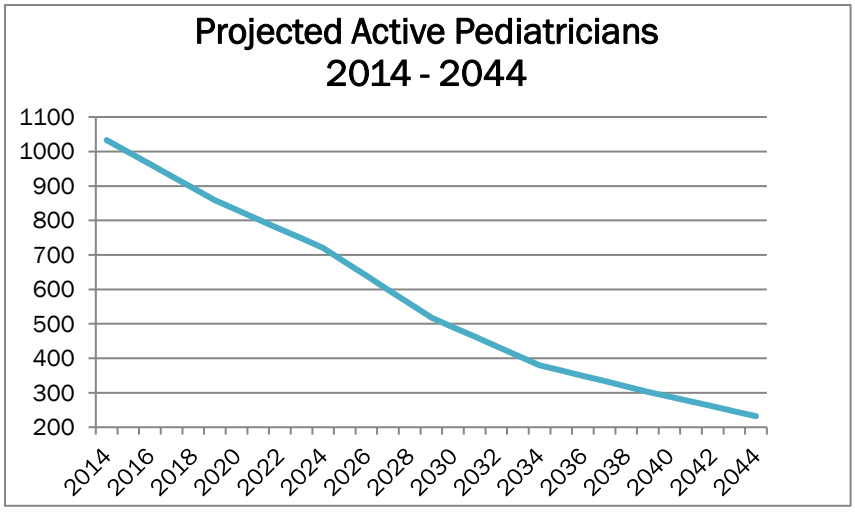
According to data from the US Census Bureau's *International Data Base*, the estimated population of children and adolescents in Puerto Rico will decrease from 859,807 in 2014 to 558,268 in 2044:

By 2044, the number of active pediatricians will have declined by 78%

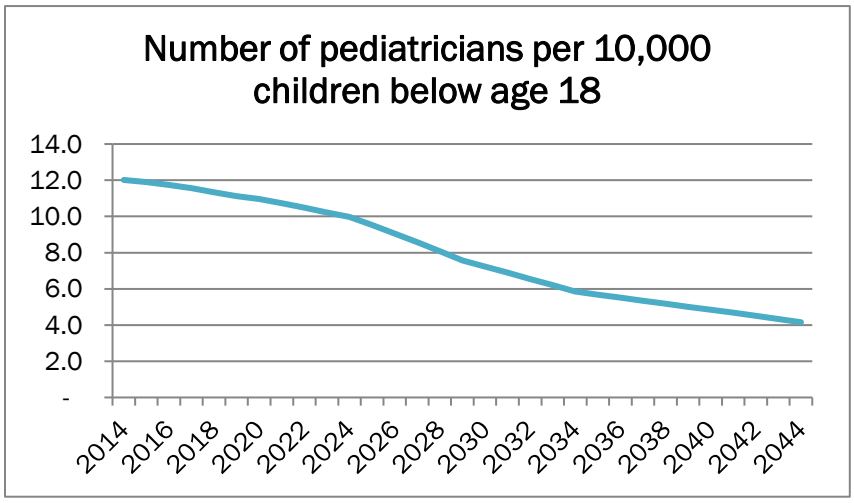


In collaboration with personnel from the Puerto Rico Statistics Institute, we estimate the number of pediatricians that could be active in Puerto Rico for that period.[20] This shows that, if current conditions are maintained, the number of pediatricians may decline in the coming decades until reaching 232 in 2044.

[20] We projected the number of pediatricians entering and leaving in order to determine the number that will be active in Puerto Rico over the next 30 years. The assumptions used: 1) Pediatricians retire at age 65, 2) only 5 pediatricians begin practicing annually [based on graduation data from the last 3 years furnished by the Licensing Board], and 3) for every 5 year period, the same number of physicians retires.



Personnel from the Statistics Institute also collaborated in establishing a projection of the number of pediatricians in Puerto Rico for every 10,000 children below age 18, as follows:



As of 2014, there were 12 pediatricians for every 10,000 children and adolescents below age 18; by 2044 this figure may decline until reaching 4.2 pediatricians for every 10,000 children and adolescents[21].

[21] If current conditions are not maintained, this may vary according to the assumptions presented. This projection is for purposes of presenting the situation these sectors may encounter and these are not official data from the Statistics Institute.

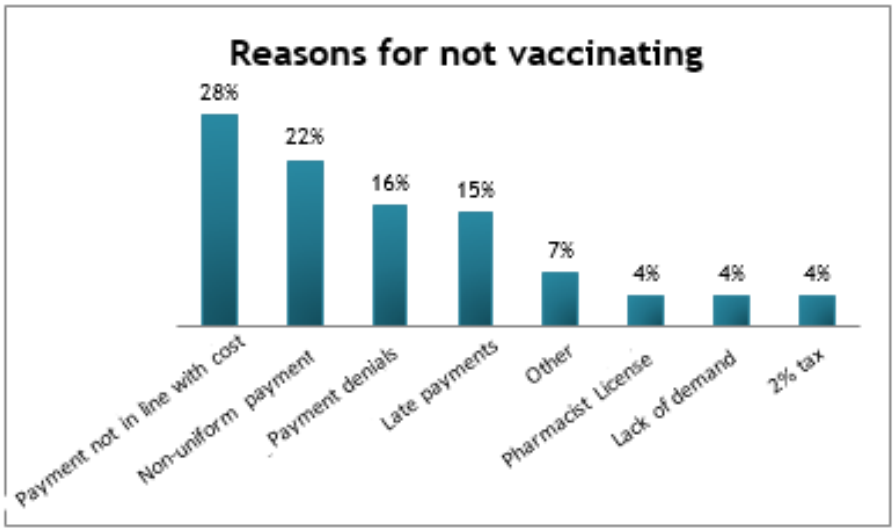
According to an interview of representatives of the Medical Association and of the AAP, pediatricians are among the medical professionals whose compensation is inadequate, as the only non-surgical procedure they can perform, in addition to their services, is immunization, and that is not cost-effective. Medicine is a long and costly field of study, for which is expected remuneration which recompenses the time and expense invested.

A similar situation was highlighted by the press on February 10, 2015, when the President of the AAP noted that the number of pediatricians having offices in the community has decreased. He also stated that many pediatricians have terminated their practices, that new pediatricians are not being trained, that they leave for the United States and those that remain decide to pursue a subspecialty.

Another aspect affecting private patients is noncompliance by private insurers with the recommended immunization service coverages, with no copayment, as required by Public Law 194 – 2011, Health Insurance Code of Puerto Rico.

In the survey conducted, participating physicians indicated the primary reasons for which they do not provide immunization services, as follows:

Economic factors are the primary reasons for not providing immunization services.



Of the eight the reasons indicated for not providing vaccination services, 6 (75%) are associated with economic factors. Of these, 4 are related to reimbursements by insurers, 1 with the lack of demand for the service and 1 to the annual tax applied to businesses.

According to information provided by the physicians participating in the survey we performed, and by Medical Association and AAP interviewed by our auditors, the economic reasons arising from problems with reimbursements by insurers affect the ability to provide immunization services to private patients.

In a document dated March 30, 2009 by the AAP it was established that, as part of the cost of maintaining immunization services, direct and indirect costs are incurred. This entity estimates that indirect costs fluctuate between 17 and 28% in addition to the cost of the vaccine. These indirect costs include administrative personnel or the time used by the physician to order and maintain the vaccine inventory, storage (electricity, refrigeration equipment and the required power generator), insurance for the vaccine inventory to protect against losses caused by temperature changes affecting the effectiveness of the vaccines, and contingency costs for losses due to nonpayment, theft or other circumstances.

We compared the cost contracted with 5 insurers as of 2015 with the estimated cost for physicians to acquire and store vaccines at their offices or medical centers. The number of vaccines evaluated and the reimbursed cost was obtained from insurer contracts with a physician we consulted. We evaluated the cost for between 12 and 14 vaccines, since contracts do not reflect the 15 vaccines that are recommended by the ACIP. The cost of vaccines was established according to the price published on the CDC webpage for private providers in 2015.

Insurer reimbursement should be 125% of a vaccine's cost.

According to AAP estimates, for direct and indirect costs to be covered, insurer reimbursement should be 125% of the cost of the vaccine. For this analysis we did not consider the cost of administering the vaccine,

due to the fact that a payment considered reasonable is established for administration of the vaccine. In the following table we present the comparison:

Insurers in P.R. cover between 79 and 93% of a vaccine's cost.

Insurer	Number of vaccines evaluated	Cost of vaccines evaluated	Indirect costs estimated at 25%	Total estimated cost to physician	Payment by Insurer	Difference in reimbursement	Estimated percent of cost covered by insurer
A	14	$974	$244	$1,218	$1,038	($180)	85%
B	12	855	214	1,069	$849	(220)	79%
C	12	855	214	1,069	$949	(120)	89%
D	12	855	214	1,069	$925	(144)	87%
E	12	855	214	1,069	$993	(76)	93%

This comparison revealed that insurance companies cover between 79 and 93% of a vaccine's estimated cost. However, this cost may vary subject to the business volume of the medical office or health clinic. The higher the number of patients seen, the more these indirect costs decrease and are covered with greater cost effectiveness. On occasion, physicians or clinics charge these differences to the private patient in the form of deductibles, and the patient is required to pay the deductible in order to receive the service.

4% of those surveyed also mentioned as a reason for not vaccinating, the restriction of having to obtain a pharmacist license in order to maintain an inventory of vaccines at an office or medical clinic. The Puerto Rico Legislative Assembly understood that this was one of the obstacles for access to immunization and addressed this through *Public Law 95-2014,* which amended *Public Law 247-2004, Puerto Rico Pharmacy Law*, to eliminate that requirement for physicians, dentists and podiatrists. This initiative was endorsed by the Department, the Medical Association, the AAP and other related associations. However, it was opposed by the Puerto Rico Pharmacists Association, which argued that a pharmacist license was a tool for control and oversight of the handling of drugs and of the installations where they were stored. Moreover, they did not consider it burdensome to obtain the license.

We cannot determine the real impact of this new legislation on access to immunization services, as the legislation is still in the implementation process.

In a nutshell, the reasons indicated by physicians in the survey conducted led some physicians to not provide services or to provide only vaccines that are profitable for their operations.

The Division of Immunization has not been effective at promoting participation in immunization by private providers.

Through the physician survey and interviews with providers, we found that in 17 of the 78 municipalities (22%), there is a lack of immunization service providers for private patients:

22% of municipalities in PR did not have providers available to attend private patients.

Ceiba, Ciales, Culebra, Florida, Guánica, Hormigueros, Lajas, Las Marías, Maricao, Maunabo, Morovis, Peñuelas, Rincón, Salinas, Santa Isabel, Vieques[22] and Villalba.

In the case of public beneficiaries, these have access to a provider contracted in each one of the municipalities. This is according to information provided by the division of immunization.

When the physician for the private patient fails to provide the service, parents or guardians must search for other providers to obtain the

[22] At the time of our evaluation, the Vieques EC Center, which sees both private patients and public beneficiaries (*VFC* Program), was not providing services due to problems with the refrigerators where the vaccines were stored.

vaccine they need. This may mean that they have to travel to other towns.

This has also caused private patients to obtain immunization services in 330 Centers, which are authorized to provide these services to public beneficiaries, the uninsured, or those with limited insurance coverage. This is done with vaccines acquired by *VFC* Program funds.

According to federal regulations, in order for a private patient to obtain such services, the patient must have no insurance or his/her private insurance has limited coverage. However, health insurance plans[23] in Puerto Rico are required to provide immunizations recommended by the ACIP and by the Advisory Committee on Immunization Practices.

In those cases, private patients asked their insurance company for a certificate of coverage in which were established limitations on vaccine coverage and they would submit the same to the 330 Center where they would administer the services.

This situation may lead to the use of federal *VFC* Program funds for purposes that are ineligible pursuant to regulations. **[See Observation 1]**

Since 2007, the VFC Program has not provided vaccines to private patients.

According to information published in a newspaper article on March 6, 2008, in December 2007, on instructions from the Federal Government, the Department ceased to provide vaccines acquired with *VFC* Program funds to private patients. This caused immunizations for private patients below age 18 to become available only at Immunization Centers and at 60 pediatricians throughout the island, which aggravated the already existing crisis.

The Department is responsible for safeguarding the health of the population and these efforts include required immunizations. This is why, during 2008, it took the initiative of serving as intermediary for access to immunization services for private patients. To do so, it began to open immunization centers known as Esteban Calderón Centers (EC

[23] See footnotes 13 and 14

Center) in the towns where such need was identified. The first EC Center was established in Bayamón, as it was identified that the neediest population at that time was that of the metropolitan area. Later, 4 centers were opened in Arecibo, Ponce, Mayaguez and Las Piedras. Following that, 1 center was opened in Vieques, for a total of 6 centers around the Island. Of these, 3 are also *VFC* providers.[24]

With respect to the Department's effort, presented in that article, the Patient Advocate at that time stated:

> This plan will significantly reduce immunization delays and in turn will allow children to continue to receive their vaccines as part of their pediatric care visits, enabling preventive pediatricians to resume immunization. [sic]

The then First Lady was also quoted, who stated:

> Our goal is for 100% of children with private plans that have immunization coverage to be able to access the services the moment they need them.

The Division of Immunization has not been effective in its oversight of compliance by private providers, schools and other centers with the registration of immunization information in the PRIR.

The Federal Government requires the Department to maintain an electronic system which allows for control of the vaccines that are supplied to public beneficiaries. For this purpose, through *Administrative Order No. 262* issued on July 18, 2009, the then Secretary of Health established that all providers (public and private) that provide immunization services must record in the *PRIR* all immunization data they may have available on their patients.

As of November 2014, 63% of the population had been registered in the *PRIR*.

The number of persons registered in the *PRIR* has increased in recent years. As of November 30, 2014, 63% of the general population had been registered. This registry is a tool that helps maintain information regarding immunization in Puerto Rico. However, most of those

[24] See footnote 22.

registered are public beneficiaries, as the Federal Government requires compliance with the same. The Division of Immunization faces the difficulty of the fact that not all physicians attending private patients, schools and all other centers comply with the registry as the Law requires.

44% of schools, preschools and daycare centers failed to comply with *Public Law No. 25.*

Pursuant to *Public Law No. 25*, schools (public and private) and preschools, day care and social treatment centers must submit a report to the Department in which they note immunization-related information. Regulation 1968[25], approved on July 11, 1975 by the secretaries of Health and of Education[26] establishes the procedures that entities must follow to meet that requirement. [See Observation 2] In 2014, 44% of these entities failed to meet this requirement.

By letters dated May 30, 2012 and 2013, and July 8, 2014, the acting secretaries of Health notified the secretaries of Education and of the Family, the ACUDEN Administrator, and the President of the Puerto Rico Council on Education; the schools, centers and universities that failed to comply with registration in the *PRIR* during academic years 2011-2012 and 2013-2014, that entry of the data into that registry replaced the requirements established under Article 9 of *Public Law No. 25*. [See Observation 3]

During our audit we were unable to obtain data from the departments of Health and of Education on immunization of homeschooled children and adolescents, as there is no information available regarding this sector. *Public Law No. 25* does not require Compliance with immunization until these students enter a school system or university, unless they meet some of the exceptions established by the *Law*. These exceptions are for religious or clinical reasons. In the case of religious reasons, an affidavit is required in which it is stated that they belong to a religious organization whose dogma conflicts with immunization. In the case of clinical reasons, a certificate signed by a physician is

[25] To establish and regulate the immunization process among children beginning primary schools in the schools of the Commonwealth of Puerto Rico, issued pursuant to Public Law No. 235 and acted on June 23, 1975.
[26] At the time, Public Instruction.

needed, which indicates that one or more of the immunizations required by the Secretary of Health may be detrimental to a student's health.

The Statistics Institute's *Statistical Quality Standards Regulations*, approved on August 8, 2008 by the Executive Director and by the President of the Statistics Institute's Board of Directors, established that the statistics compiled must be complete, reliable, and quickly and universally accessible.

Having these statistical data available may help government agencies and the Legislative Assembly to establish public policy on matters affecting this sector. Additionally, in the event of epidemics, the Secretary of Health can determine the population areas and sectors at greatest risk. Further, this allows the Government to exercise its duty to ensure protection of the rights of children participating in this study alternative.

Comments from Management

Among other things, the Secretary of Health stated in her letter:

> [...]
>
> The Division of Immunization has been working to resolve the situation of access in the private sector with different strategies. The department took the initiative to intervene in the situation with the private sector and serve as facilitator, assembling and creating work groups and alliances with interest groups. As a result of these efforts the Immunization Centers were established, the situation with the pharmacist license with Law 95-1014 in the meeting that requirement. [sic]
>
> [...]
>
> It is important to note that there are situations that are outside of the control of the Division of Immunization such as the fact of the file in the number of new pediatricians every year and the decrease in the number of these professionals, as well as of the amounts paid them by insurance companies.

[...]

We accept the observations and recommendations of your audit, with the above-mentioned explanations and we are working arduously so that the population of Puerto Rico may have immunization services available to it, without barriers. [sic]

See recommendations 1, 2 and 7.

Result 2 - Evaluation of the Division of Immunization's Performance System

Reasons:

1. Lack of orientation by the OMB.
2. Absence of oversight procedure
3. Absence of adequate guidelines for measurement.

The Division of Immunization's Performance System is ineffective, because it does not contain the elements needed to measure its activities, objectives and goals.

This is contrary to *Law 236-2010*, *Government Program Execution and Accountability Act*, as amended. **[See Observation 4]**

In our evaluation of the same we determined that the OMB did not properly orient Department personnel about important technical aspects related to preparation of the Strategic Plan, of the Annual Execution Plan and of the Results Report. Nor did it establish an oversight procedure for the implementation of the elements of the performance or accountability system. Furthermore, we determined that *Circular Letter 97-12*[27]*, New Guidelines for the Preparation and Presentation of Strategic Plans, Annual Execution Plans and Results Reports, Pursuant to Public Law No. 236-2010*, issued on March 19, 2012 by the OMB, does not contain the elements required by *Law No. 236-2010* nor does it establish adequate guidelines that allow for measurement of the efficiency, efficacy and accountability. **[See Observation 5]**

Law 236-2010 provides that every government agency must implement a program directed at optimizing its operations and service through

[27] Repealed Circular Letter 95 – 11 enacted on December 22, 2011.

strategic plans that contain quantifiable objectives. This is for purposes of improving efficiency and the public's perception of the Government. Further, it establishes that this mechanism serves the purpose of implementing a government transparency and accountability system, which allows for determination of the efficiency and efficacy of services through the publication of results and of the quality of the same.

Further, this *Law* empowers the OMB to prepare any regulations or guidelines needed for their implementation.

Comments from Management

The Secretary of Health stated in her letter, among other things:

> The Division of Immunization acknowledges the limitations of technical knowledge of the development of strategic plans and execution plans, for the period audited. For such reason, the formats provided by the OMB were used for the development and completion of the same. [...] However, the efficiency and efficacy of the division's performance was and is evaluated at least annually by the federal government, which is the Division's primary sponsor. [...] It should be noted that the Division focused on the years audited to document primarily the requirements of the federal government which respond to federal objectives and goals. [sic]

See recommendations 4 and 14.

Result 3 - Evaluation of the results and of the execution of the Division of Immunization in compliance with its Annual Execution Plan 2012-13.

Our auditors evaluated the Division of Immunization's Annual Execution Plan 2012-2013 with the goal of verifying its performance for that fiscal year in accordance with the four strategic goals established therein. Those goals established that, by June 30, 2018, the Division of Immunization hopes to have achieved the following:

- **Strategic goal 1** - 90% of children will have completed Series 2[28] vaccines at 35 months.
- **Strategic goal 2** - 70% of adolescents between 13 and 15 years of age will have been administered vaccines for meningococcal meningitis, tetanus, diphtheria and whooping cough, and the first dose of the vaccine against the human papilloma virus, as well as the varicella vaccine.
- **Strategic goal 3** - 50% of patients aged 65 and older will be vaccinated annually against influenza.
- **Strategic goal 4** - 51% of the population will be registered in the Puerto Rico Immunization Registry.

The Department did not submit to the OMB a results report for fiscal year 2012-2013, so we are requesting that the Division Director certify the results for each one of the goals, objectives and activities. Further, we interviewed the employees and officials of the Division and we requested additional information in order to corroborate the results.

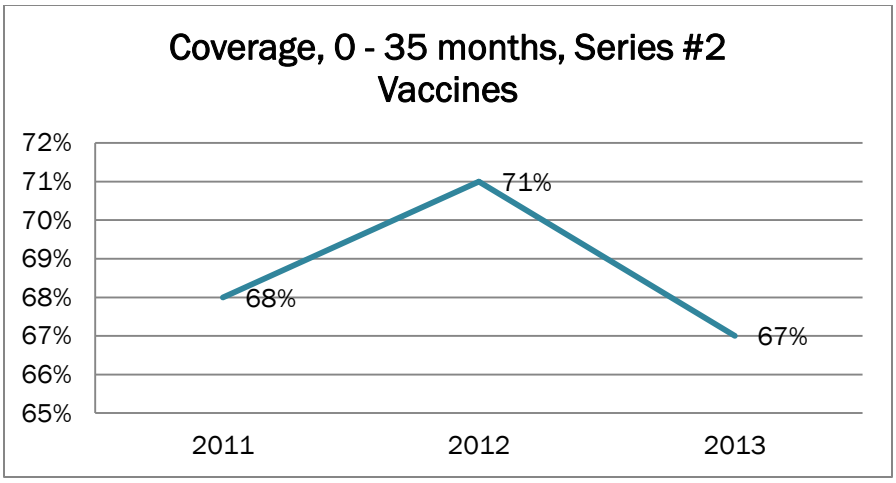
The accountability system and the results certified did not allow us to measure the efficiency and efficacy of the division of immunization's execution for 22 elements included in the Annual Execution Plan 2012-2013. **[Observation 6-b.]**

Moreover, we evaluated the effectiveness of progress towards meeting the four strategic goals for fiscal year 2012-2013.

During that year the division was not effective at making progress in the execution of Strategic Goal 1. The following Results were achieved:

[28] Series 2 includes 4 doses of the vaccine against diphtheria, tetanus and whooping cough; 3 doses of the polio vaccine; 1 dose of the vaccines against measles, German measles and mumps; 3 doses of the vaccine against invasive disease from Haemophilus Influenzae Type B vaccine; 3 doses of Hepatitis B vaccine; 1 dose of varicella vaccine; and 4 doses of the vaccine against invasive disease from Streptococcus Pneumoniae.

They were not effective at advancing Goal 1.



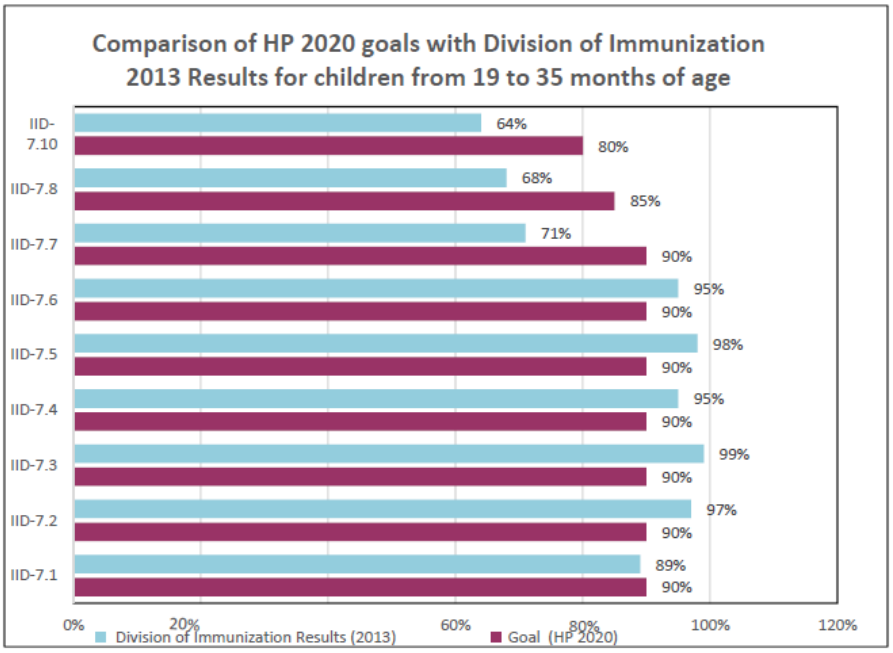
This shows that for fiscal year 2012-2013, there was a 4 percentage point decline in Series 2 coverage as compared to 2011-12, and a 1 percentage point decline compared with 2010-11. This execution does not provide progress sufficient to meet the proposed 90% coverage goal by June 30, 2018. **[Observation 6-a.]**

We compared the results obtained by the Division of Immunization with the goals established in the Healthy People 2020 (HP 2020) objectives. HP 2020 is a framework for action established by an interagency group, in collaboration with the Federal Department of Health and other federal agencies, which establishes goals for specific objectives in certain areas of health which are considered necessary and which should be attained by 2020. For the group from 19-35 months of age, the objectives are as follows:

Healthy People 2020 Objective
IID-7.1 Maintain an effective coverage level of 4 doses of the diphtheria-tetanus-acellular pertussis (DTaP) vaccine.
IID-7.2 Achieve and maintain an effective vaccination coverage level of 3 or 4 doses of Haemophilus influenzae type b (Hib) vaccine.
IID-7.3 Maintain an effective vaccination coverage level of 3 doses of hepatitis B (hep B).

Healthy People 2020 Objective
IID-7.4 Maintain an effective coverage level of 1 dose of measles-mumps-rubella (MMR) vaccine.
IID-7.5 Maintain an effective coverage level of 3 doses of polio vaccine.
IID-7.6 Maintain an effective coverage level of 1 dose of varicella vaccine.
IID-7.7 Achieve and maintain an effective coverage level of 4 doses of pneumococcal conjugate vaccine (PCV).
IID-7.8 Achieve and maintain an effective coverage level of 2 doses of hepatitis A vaccine.
IID-7.9Achieve and maintain an effective coverage level of a birth dose of hepatitis B vaccine (0 to 3 days between birth date and date of vaccination).
IID-7.10 Achieve and maintain an effective coverage level of 2 or more or 3 or more doses rotavirus vaccine.

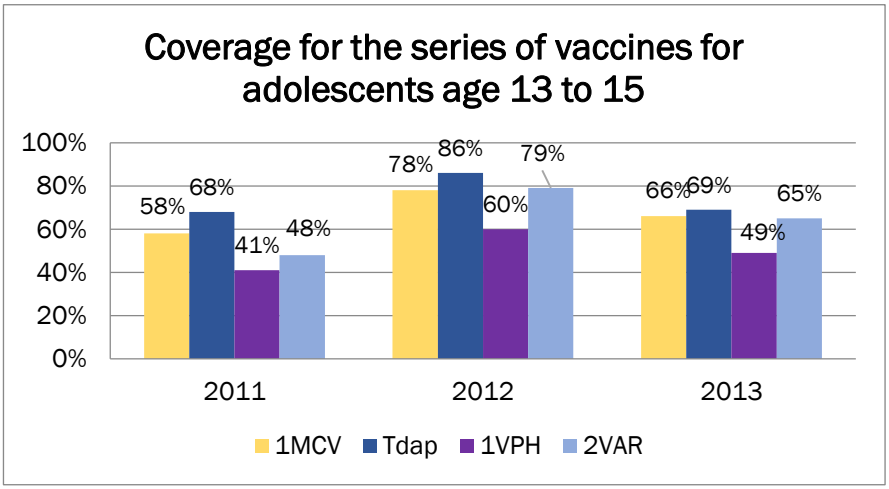
We compared the results of HP 2020 with Division statistics for that group; the result is presented in the following graph:



For goal 7.9, the division had no data available. Coverage in Puerto Rico was met or exceeded in 6 (67%) of the 9 HP 2020 objectives evaluated. In objective 7.1, which established a goal of 90%, there was a coverage of 89%, which we consider to substantially meet the goal.

Effective in terms of advancing Strategic Goal 2.

For the fiscal year 2012-13, the division was effective at achieving progress in the execution of Strategic Goal 2. The following results were attained:

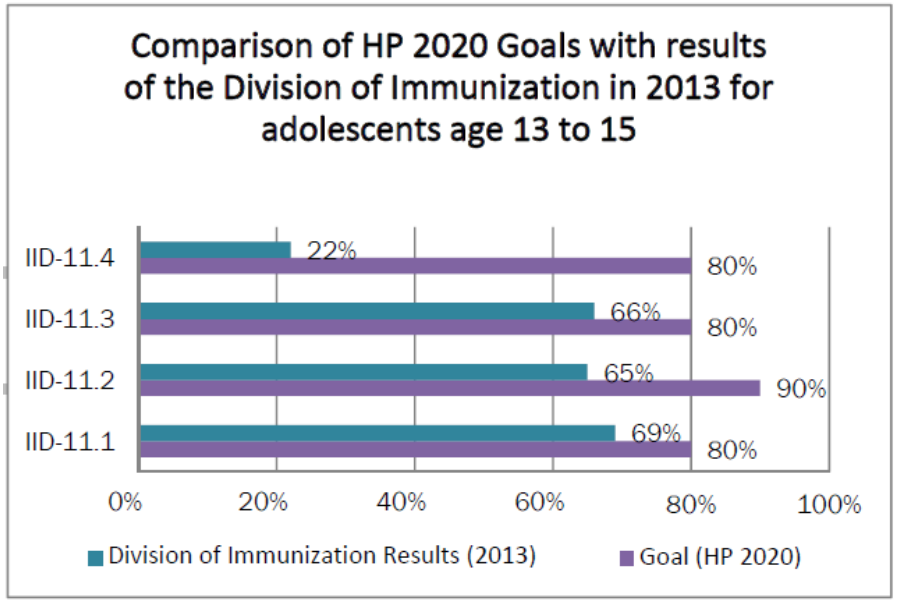


Although in 2013 there was a decline in coverage of between 11 and 17 percentage points, the division established a 70% coverage goal for each of the antigens by June 30, 2018. For the Tdap vaccine29, the result was 69%, which is 1 percentage point below what was established. For the 2 doses of VAR[30] vaccine, the result was 65%, that is, 5 percentage points below. For the MCV[31] vaccine the division reported 66% coverage, which is 4 percentage points below what is established. As for coverage of the 3 HPV[32] vaccine the Division reported 49%, which is 21 percentage points below what was established. However, we conclude that such coverage may allow the division to reach the established Strategic Goal by June 30, 2018. We compared the data reported for Puerto Rico with the following HP 2020 objectives:

[29] Tetanus, diphtheria, pertussis.
[30] Varicella
[31] Meningococcal
[32] Human Papilloma Virus.

Healthy People 2020 Objective
IID-11.1 Increase the vaccination coverage level of 1 dose of tetanus-diphtheria-acellular pertussis (Tdap) booster vaccine for adolescents.
IID-11.2 Increase the vaccination coverage level of 2 doses of varicella vaccine for adolescents by age 13 to 15 years.
IID-11.3 Increase the vaccination coverage level of 1 dose meningococcal conjugate vaccine for adolescents by age 13 to 15 years.
IID-11.4 Increase the vaccination coverage level of 3 doses of human papillomavirus (HPV) vaccine for females by age 13 to 15 years

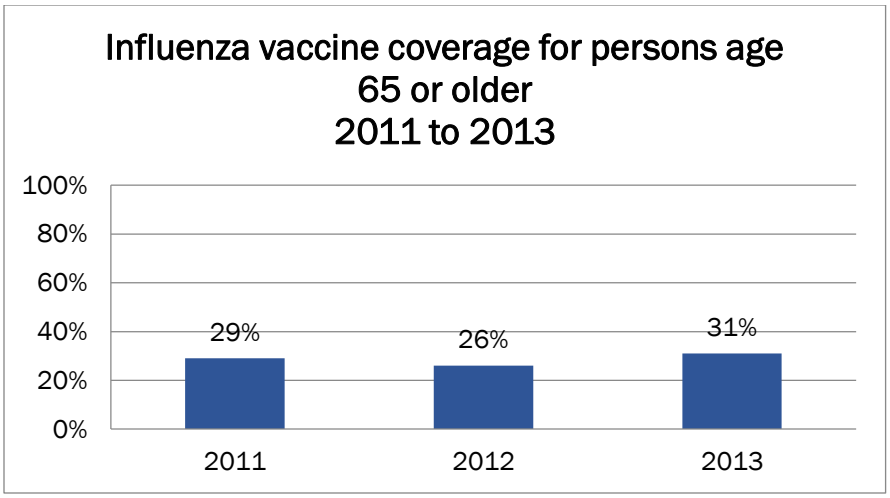
The result of the comparison was as follows:



This shows that for objective 11.4 the Puerto Rico result is 58 percentage points below what is expected under HP 2020. For this vaccine, action must be taken that is effective at orienting and providing access to services in order to increase coverage.

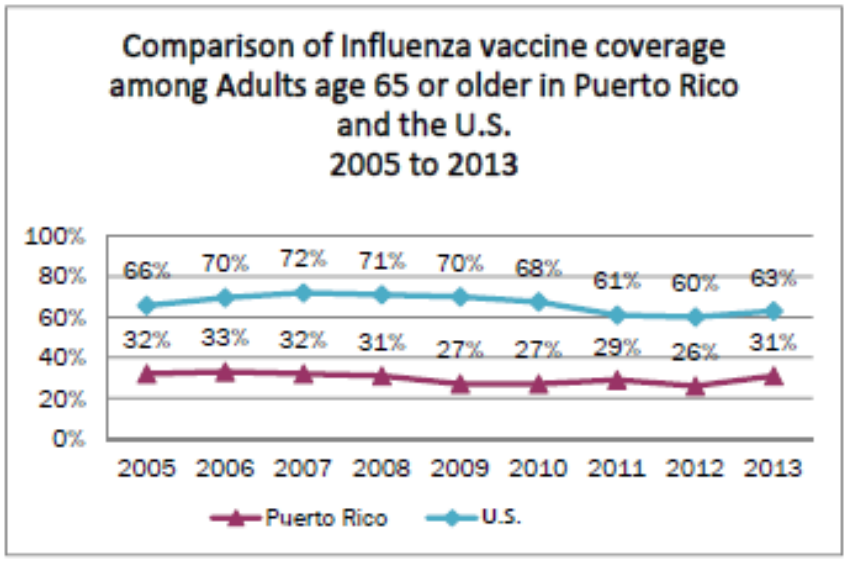
They were not effective in advancing Strategic Goal 3.

In fiscal year 2012-13, the division was not effective at achieving progress in the execution of Strategic Goal 3. This Goal is related to influenza vaccination for adults age 65 or older. The results were as follows:



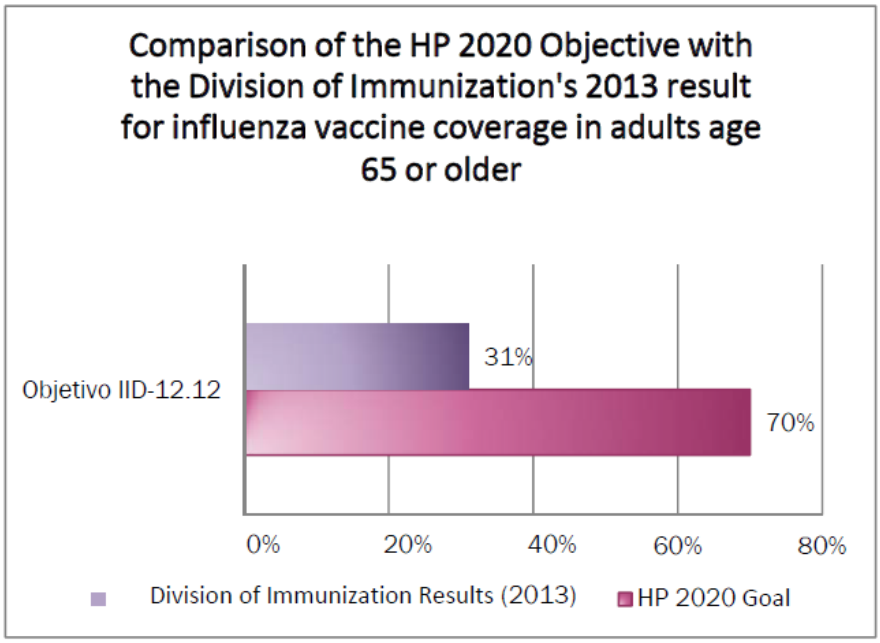
By 2013, the Division showed a 5 percentage point increase as compared to the 26% obtained in 2012, and a 2 percentage point increase above the 29% reported for 2011. [Observation 6-a.] However, this result does not show sufficient progress toward meeting Strategic Goal 3 by June 30, 2018, which establishes that 50% of patients age 65 or over should receive an influenza vaccine annually. This is due to the fact that we considered, that the Division should reach, at the least, 35% coverage in order to consider that its execution is on the path to meeting the established goal.

Below we compare the Puerto Rico results with those of the United States for that coverage:



Influenza vaccine coverage in Puerto Rico has remained below the level reached throughout the United States. Access to this vaccine for adults age 65 or older should not be an issue, as pharmacists are authorized to administer vaccines to those age 18 or older, pursuant to *Public Law No 247-2004, Puerto Rico Pharmacy Act,* and *Regulation No. 7902, to Regulate the Operation of Drug Manufacturing, Distribution and Dispensation*, approved on August 3, 2010 by the Secretary of Health.

We compared the 2013 result with HP 2020's objective IID-12.12. This objective seeks to reach and maintain 70% vaccination against seasonal influenza for adults age 18 or older.[33] The result of the comparison is as follows:



The data show a difference between what was established, and what was achieved, for this vaccination.

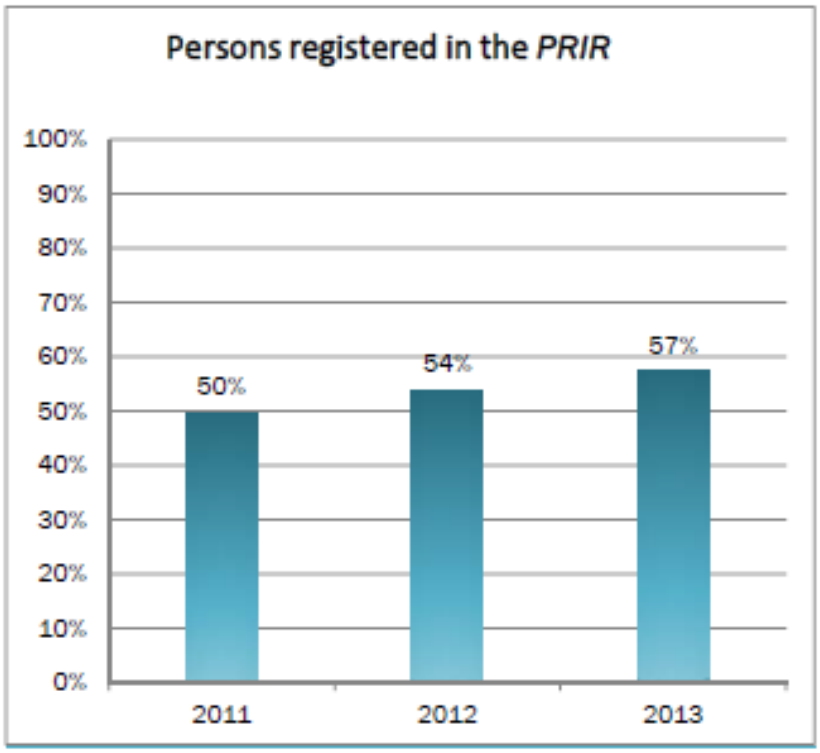
According to the Weekly Report (Partial) Influenza Monitoring in Puerto Rico from December 21 to 27, 2014, in 2014 23,094 cases of influenza were reported, which required 981 hospitalizations. Moreover, 13

[33] With respect to vaccination against seasonal influenza, in 2013 HP 2020 established a single objective for the population of adults age 18 and over. For that year, available data at the Division of Immunization included only the population of adults age 65 or older.

deaths were reported due to influenza-associated causes. For this reason, it is considered important to search for alternatives for increasing influenza vaccine coverage in all age groups.

They were effective in advancing Strategic Goal 4.

As for Strategic Goal 4, the Division was effective in its execution, according to data from the report the *PRIR*'s IIS Stats. The results were as follows:



This represents a seven percentage point increase compared to fiscal year 2010-11, and the established goal of 51% by June 30, 2018 was exceeded by 6 percentage points. By 2014, 62% of the population had been registered. However, we believe that this Strategic Goal should be revised in order to establish greater coverage in the registry, which would be a goal that is tempered to reality in the Division's operation and ongoing progress with the same.

The Division was also effective in meeting performance goals 1.1.1 and 2.1.1, to orient 100% of providers under the Health Plan in order to ensure that they offer provide services pursuant to the ACIP, the CDC and Administrative Order 262. Moreover, it was effective in meeting

Performance Goal 4.2.1, to promote *Administrative Order No. 262* and *Public Law 40-2015*, *Health Information Electronic Exchange and Administration*, the purpose of which is to ensure that all immunization service providers comply with the same and enter their patients' immunization into the Puerto Rico Immunization Registry.

Comments from Management

The Secretary of Health stated the following in her letter, among other things:

> Immunization coverage in children is measured for series 1 and 2, established by the CDC, and coverage is also measured for each antigen separately. In Series 2 by 35 months of age, 67% was attained, [...] but for each individual vaccine with the exception of PCV (pneumococcus), coverage is over 90%. This has an explanation, which is that if for any reason (medical or other), a child does not receive a dose of the PCV vaccine at the proper age or starts the series a little later, s/he will not need to receive the entire 4-dose series of this vaccine. The child would end up with three doses of PCV and would be adequately vaccinated. [...] [sic]

See Recommendation 6.

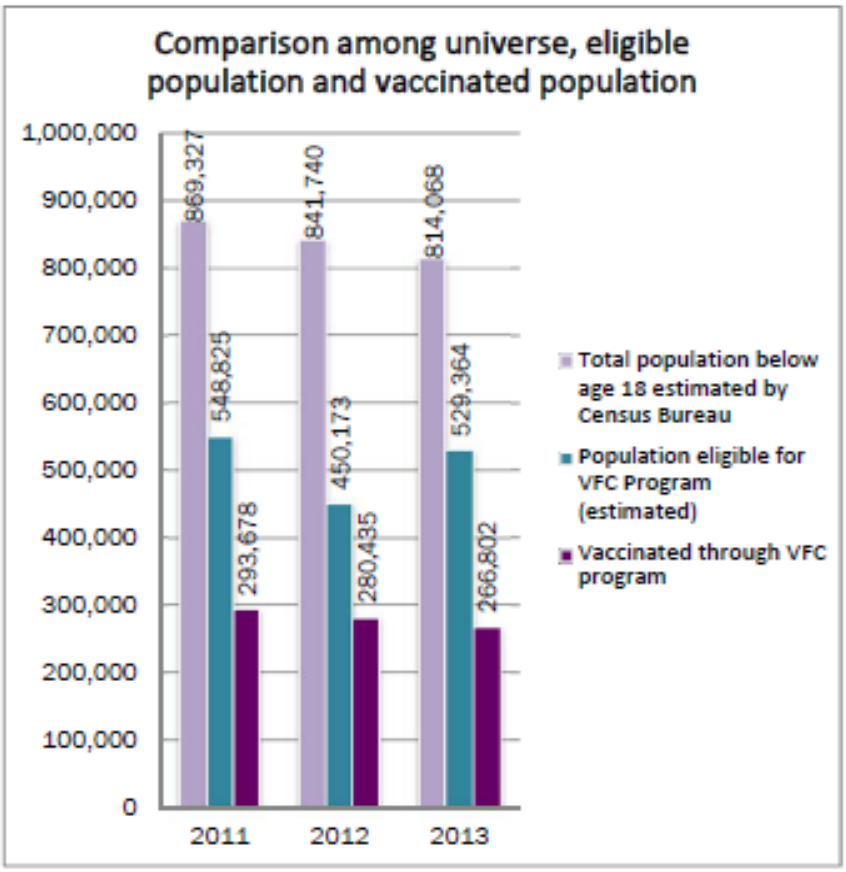
Result 4 - Evaluation of the principle of economy in the movement of federal *VFC* program funds

The Division of Immunization meets the principle of economy in the execution of the VFC Program.

This is so because in 2013, the average cost per beneficiary of the same was less than the average cost for 2011. Further, the cost to vaccinate a child below age 18 through this Program is less than the cost for a private patient.

We evaluated the economy of the *VFC* Program in Puerto Rico from 2011 to 2013. To do so, we requested information related to total

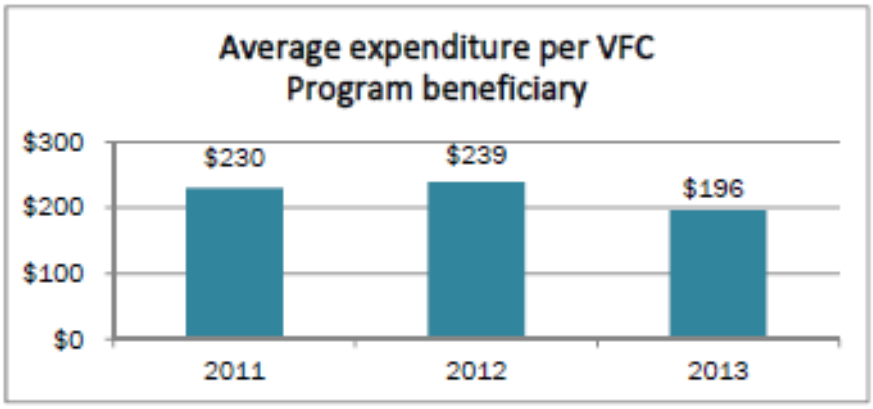
expenses[34] for the *VFC* Program and total beneficiaries of the same. Below we present a comparison between the total population[35] below age 18, the eligible population estimated by the *VFC* Program and the number of beneficiaries vaccinated through that Program:



We determined that, from 2011 to 2013, through the *VFC* Program, the division of immunization received $67,646,169, $66,946,700, and $52,212,188, respectively. These funds were used to vaccinate 293,678, 280,435; and 266,802 children and adolescents during those years. Based on these data, the average expenditure per beneficiary per year was $230, $239 and $196, respectively, as shown in the following graph:

[34] Including administrative expenditure for operating the *VFC* Program and vaccine purchasing expenditures.
[35] According to the Census Bureau at its webpage www.census.gov.

The average cost per participant declined by 15%.



This reflects a 15% reduction in the average cost per participant from 2011 to 2013. Several factors can be considered to have brought about this result, including the fact that during that period the number of beneficiaries with at least one vaccine in each year, Fell by 9.2% from 293,678 to 266,802, which led to a reduction in the amount of funds for the program, since funds requested depend on the number of beneficiaries attended. This reduction in the number of beneficiaries could be due to the fact that between 2011 and 2013, there was a reduction in the total population of children and adolescents below age 18. This number declined by 6.4%, from 869,327 in 2011 to 814,068 in 2013.

Further, we conducted an analysis of the estimated cost to vaccinate a child from birth until age 18, both for the *VFC* Program[36] for private patients in the United States and in Puerto Rico. The Schedule of Vaccines was used, as recommended by ACIP and the Secretary of Health, except for the recommended influenza vaccine, as indicated:

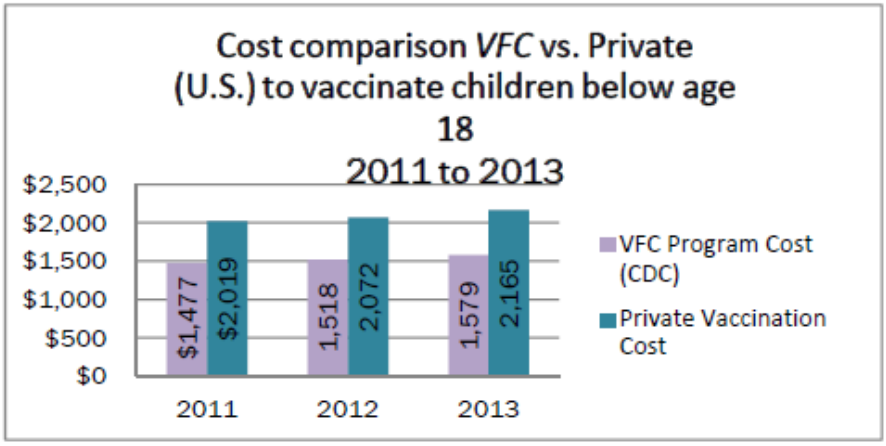
[36] Prices for vaccines acquired by the *VFC* Program are established through contracts negotiated by the U. S. Secretary of Health and Human Services (Federal Secretary of Health) and the CDC.

Antigen or Series	Vaccine(s)	Recommended Dose
DTaP	Diphtheria, tetanus and pertussis	2
DTaP-IPV	Diphtheria, tetanus, pertussis, and polio	1
DTaP-Hep B-IPV	Diphtheria, tetanus, pertussis, hepatitis B and polio	1
DTaP-IP-HI	Diphtheria, tetanus, pertussis, polio and haemophilus influenzae	1
e-IPV	Polio	1
HepA	Hepatitis A	2
HepB	Hepatitis B	2

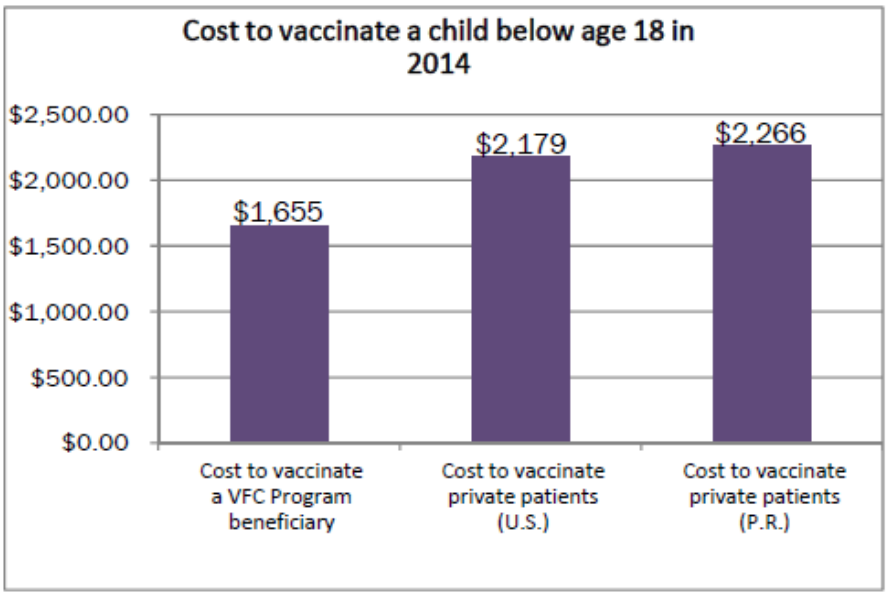
Antigen or Series	Vaccine(s)	Recommended Dose
Hib	Haemophilus influenzae type b	2
HPV	Human papilloma virus	3
MCV	Meningococcal	2
MMR	Measles, mumps and rubella	2
PCV13	Pneumococcal	4
RV	Rotavirus	2
Tdap	Tetanus, diphtheria (reduced) and pertussis	1
VAR	Varicella	2

From 2011 to 2013, the *VFC* Program acquired, through the CDC[37], vaccines at prices lower than is available for the private sector in the United States, as indicated[38]:

[37] Prices indicated on the CDC's webpage: www.CDC.gov
[38] We did not consider in this analysis the indirect costs associated with maintenance of the vaccine inventory.



We also conducted an analysis of the cost to vaccinate a child below age 18, according to 2014 prices. In this analysis we also added the cost for private patients, according to data provided by a provider and a vaccine distributor. Our analysis revealed the following[39]:



Costs as compared with those in the U. S.

According to 2014 prices, the cost to vaccinate a *VFC* Program beneficiary below age 18 was $1,655. In the United States the cost to vaccinate a private patient was $2,179, which represents $524 more than the *VFC* program cost. Further, in Puerto Rico, the cost to vaccinate a private patient was $2,266. That is, $87 more than the immunization

[39] See footnote 36.

cost for a private patient in the United States[40] and $611 more than the cost to vaccinate the same child through the *VFC* Program.

The *VFC* Program meets the principle of economy in the management of its funds. This is largely due to the fiscal control established by federal regulations which monitor and regulate the vaccine acquisition process. That set of regulations requires the acquisition of vaccines through contracts at prices negotiated by the Federal Secretary of Health and the CDC, which are requisitioned monthly with the controls established by the CDC in the amounts and monitoring of the same. The Federal Secretary of Health negotiates the prices established in the contracts according to the quantities each state requires, whose immunization program is sponsored by federal funds. This has allowed the efficient management of funds assigned to that Program.

OBSERVATIONS REGARDING RESULTS

Observation 1 – Certificates of limited coverage issued by four health insurers are contrary to Law

Pursuant to *Public Law 194-2011*, insurance companies must provide, among other services, coverage for immunizations for which there is a recommendation by the ACIP and by the Advisory Committee on Immunization Practices with zero copayment or without sharing costs.[41]

The OCS is responsible for overseeing ensure compliance with applicable law and with contracts executed with their subscribers.[42]

Our auditors found that in the 330 Centers there were 362 certificates of limited vaccine coverage issued by 4 insurance companies, from September 2012 to January 2015.

In November 2013, the Division of Immunization referred to the OCS the situation regarding insurers that were issuing certificates in which they established limitations to their coverages or to their health plan contracts for immunization services.

[40] The immunization cost in the United States is established according to prices that the manufacturers report to the CDC.
[41] See footnote 13.
[42] See footnote 14.

In *Circular Letter 2011-1816-KV* dated June 30, 2011 and in *Regulatory Letter CN-2013-162-AS* dated November 26, 2013, the OCS warned all health services organizations that the practice of establishing the limitations in question was contrary to *Law* and was causing the Government to lose funds.

The OCS levied administrative fines on 4 insurers for $160,000.

From August to October 2014, as a result of our audit, the OCS issued four cease-and-desist orders and levied administrative fines of $160,000 on four insurance companies for violations to Article 2.050 (c)(2) of *Public Law 194-2011*, and to Article 27.050 (1) of *Public Law No. 77*, for certificates contrary to the above, issued from September 2012 to October 2013. One of the insurers appealed its $130,000 fine and alleged that it had not committed the violations in several of the certificates. The OCS determined that the allegation was correct and reduced the fine to $106,274. In the end, the fine for that insurer was set at $70,000.

Of the 362 certificates mentioned, 9 were issued by an insurance company after he was notified of the cease-and-desist order by the OCS.

The subscribers of those insurance companies presented these certificates in order to obtain immunization services with vaccines acquired through federal the FC Program funds.

The Division of Immunization could not tell us the exact amount of the funds improperly used due to this situation.

Criteria

The situation in question is contrary to Article 27.050 (1) of *Public Law No. 77*, to Article 2.050(c)(2) of *Public Law 194-2011*, and to Article 7 of *Public Law 194-2000, Patient Bill of Rights and Responsibilities*, as amended.

Effects

The above resulted in following:

- Immunization services were provided to persons who do not qualify to receive them.

- Services for patients and immunization coverage levels in Puerto Rico may be affected.
- The loss of federal funds due to their misuse.
- Unjust enrichment of insurers from failing to provide the services in question to their patients.

Comments from Management

In the letter from the Secretary of Health, among other things she indicated:

> [...] After multiple attempts with the Office of the Insurance Commissioner, they began to refer the certificates to this office, in which the various insurance companies established limits on vaccine coverage for the OCS to evaluate and handle this situation with the results indicated by your audit. [sic]

In her letter, among other things the Insurance Commissioner indicated:

> [...]
>
> The non-compliance by some insurers or health insurance organizations cannot be interpreted as a direct consequence of a lack of oversight by the OCS, as they have conducted investigations and adopted several measures in order to fulfill their duty to oversee and promote access to vaccines in the private health insurance segment.
>
> [...]
> There are limited vaccine certificates that are valid because not all medical plans in the private market are required to cover vaccines.
>
> The OCS has responsibly handled the observations on noncompliance with the CSSPR's Article 2.050 and in this regard it has issued regulatory and circular letters, it has conducted investigations and people may contact the OCS's Investigations Division to receive information, among other measures adopted by the OCS.

[...]

We considered the Insurance Commissioner's allegations, but we found that the **Observation** prevails. Though it is true that the OCS has taken the action mentioned by the Commissioner in her letter, the action was not taken on a timely basis. As *Circular Letter 2011-1816-AV* makes clear, since 2011 the OCS had been aware of the situation in question. Nonetheless, according to the data presented, the practice continued in the following years and it was not until 2014 that the OCS conducted the investigation and established the appropriate fines for noncompliance by the insurance companies, that is, four months after the start of our audit and three months after our meeting with the OCS.

See recommendations 2 and 7.

Observation 2 – Failure to update and approve Regulation 1968 which establishes and regulates the humanization process for children entering primary school

On June 11, 1975 the secretaries of Public Instruction (now the Department of Education) and of Health approved Regulation 1968, to establish and regulate the immunization process for children entering primary school in any school of the Commonwealth of Puerto Rico. This was approved by virtue of *Public Law No. 235* enacted on June 23, 1974, which was repealed by *Public Law No. 25*.

As of September 29, 2014, *Regulation 1968* had not been updated to adjust it to organizational, administrative and operational changes in the departments, related to immunization. Nor was it approved by the Secretary of the Family pursuant to *Public Law No. 25*.

Criteria

The aforementioned situation is contrary to Article 1, Section 2.19 of *Public Law No. 170* enacted on August 12, 1988, *Uniform Administrative Procedures Act of Puerto Rico,* as amended*,* in which it is established that the agencies must review, every five years, the regulations to assess whether those regulations effectively follow the

public policy of the agency or of the legislation under which they were approved.

It is also contrary to Article 13 of *Public Law No. 25*, in which it is established that the Secretary of Health, together with the secretaries of Education and of Family Affairs will issue the necessary regulations in order to comply with what is prescribed in that *Law.*

Effects

The aforementioned precludes the secretaries and the departmental employees from relying on regulations adjusted to the organizational, administrative and operational changes in force, which serve as a guide to discharge their functions in an effective and uniform manner. Further, it contravened *Public Law No. 25* and it may cause the Regulation to be challenged since it does not have the approval of the Secretary of Family Affairs.

Comments from Management

In the letter from the Secretary of Health, she indicated, among the other things, that they are working to update *Public Law No. 25* and to adjust it to the current reality.

See Recommendations 3, 8 and 10.

Observation 3 – Non-Compliance by Entities with the Registration of Information in the *PRIR*

Within the 60 consecutive days following the beginning of a school term or the registration of a student or preschool child, the School Director, Registrar, Director of Social Treatment Center or Director of Day Care must file a report with the Department. Such report is prepared on the forms furnished by the Department and must indicate the number of students admitted to the entity with an immunization certificate, the number of students that have been exempted and those who have been provisionally admitted. This, as provided in Article 9 of *Public Law No. 25.*

It corresponds to the Department of Education to ensure compliance of this requirement by the public schools, to the Puerto Rico Council on Education for compliance by the private schools and universities, to the ACUDEN for the Head Start and Child Care centers that receive funding through ACUDEN[43] and to the Department of Family Affairs for the day care centers.

By letters dated May 30, 2012 and 2013, and July 8, 2014, the Department determined that this data must be reported in the *PRIR*'s electronic system.

We conducted a review of compliance with the indicated requirement by such entities. For this review we analyzed the list of public schools; of day care centers, of Head Start and Child Care centers and of active private schools and universities; also, the entities which did not report. These lists were furnished by the Data Manager of the Immunization Program and corresponded to fiscal years 2011-12 to 2013-14. Our review revealed the following:

a. For 2011-12, 1572 (30%) of 4005 entities were non-compliant, as indicated:

2011-12	Total Institutions	Number non-reporting	Percent of total Institutions
Public schools	1,473	512	35%
Head Start and Child Care Centers	875	376	43%
Daycare centers	590	338	57%
Private schools	984	290	29%
Universities	83	56	67%
Total	**4,005**	**1,572**	**39%**

[43] There are municipalities and private entities that receive the funding directly from the federal government without involvement of ACUDEN.

b. For 2012-13, 1861 (49%) of 3820 entities were non-compliant, as indicated:

2012-13	Total Institutions	Number non-reporting	Percent of total Institutions
Public schools	1447	691	48%
Daycare Centers	845	440	52%
Head Start and Child Care Centers	692	356	51%
Private Schools	751	315	42%
Universities	85	59	69%
Total	**3,820**	**1,861**	**49%**

c. For 2013-14, 1589 (43%) of 3689 entities were non-compliant, as Indicated:

2013-14	Total Institutions	Number non-reporting	Percent of total institutions
Public schools	1,447	624	43%
Head Start and Child Care Centers	769	332	43%
Private Schools	689	278	40%
Daycare Centers	699	335	48%
Universities	85	20	24%
Total	**3,689**	**1,589**	**43%**

Criteria

The situation found is contrary to Article 9 of *Public Law No. 25.*

Effects

The aforementioned precludes the Secretary of Health from having precise and up-to-date information on the levels of immunization with

which to make decisions and to be able to address, in a timely manner, the related situations that may arise. Nor does it allow him/her to efficiently monitor compliance of the provisions in *Public Law No. 25.*

Comments from Management

The Secretary of Health noted in her letter, among other things, that there is proposed legislation that considers the importance of the *PRIR* as an instrument to produce reports about the status of immunization of the population.

In the letter from the Secretary of Health, she indicated, among other things, that via *Circular Letter 35-2013-2014* from June 4, 2014, it was established, as protocol, that the School Director has the responsibility to prepare, within the first 60 days of the school year, a report about the students who need to complete the series of immunizations on the form that the Department provides. Further, that the School Nursing Program coordinates with the Department, the guidance about the mechanization of the Immunization Report from August to November of every school year.

In the letter from the Administrator of the ACUDEN, she indicated, among other things, the following:

> [...] it should be noted that ACUDEN is not the exclusive provider of early childhood services in Puerto Rico and the organic law of the Department of Family Affairs does not grant it the power to oversee the operation and compliance of the care centers with the legislation and regulations in force and applicable to that sector. [sic]
>
> [...]
>
> A study of the lists of institutions that allegedly did not comply with the duty to register the immunizations shows that there are many institutions, public and private, that do not have any ties with the ACUDEN, but still, responsibility is assigned to the Agency. That is to say, there are municipalities and private entities that for the described period have or had concessionary

> relationship with the federal government and received funding directly, without intervention from the ACUDEN and other private centers that were classified as care centers or Child Care, but did not have any type of relationship with the ACUDEN. [sic]
>
> [...]
>
> The reports sent to the attention of the ACUDEN by the Department of Health do not differentiate between private and public institutions not related to the Agency and in some cases, as happened in 2011-12, more than 25% of the institutions that did not report data in *PRIR* are not related to the ACUDEN. [sic[
>
> [...]
>
> Proactively, a collaborative agreement will be coordinated with the Division of Immunization of the Department of Health, through which, the childcare centers that receive federal funding through the ACUDEN can be identified and segregated. Similarly, access will be requested to the *PRIR* system in order to monitor compliance with data entry into the system, since the notice that the Department of Health sends out about alleged noncompliance is done once the school year ends. [...][sic]

In the letter from the Executive Director of the Puerto Rico Council on Education, he indicated, among other things, the following:

> [...] we must point out that Law 25 does not specify that the Puerto Rico Council on Education must oversee the entities under our jurisdiction in regards to compliance with that law, and neither does our enabling Law, Reorganization Plan Number 1, of 2010, indicate it. Nevertheless, we know the importance of the institutions complying with the requirements of Law 25 and we have collaborated with the Department of Health to bring it the information about the institutions as it is requested. [sic]
>
> The CEPR complied with: providing the lists of the educational institutions to the Department of Health with their registration, as requested, and sending the notices and

> communication from the Department of Health to the educational institutions. [...] [sic]

We considered the allegations by the Administrator of the ACUDEN and by the Executive Director of the Puerto Rico Council on Education, but we determined that the **Observation** prevails. This, because the institutions of care or education to which reference is made in the **Observation,** are those for which oversight corresponds to either the Department of Education, the Department of Family Affairs, the Puerto Rico Council on Education or the ACUDEN.

See Observations 9 and 11 to 13.

Observation 4 – Deficiencies related to the preparation of the Strategic Plan 2011-18 and the Annual Execution Plan 2012-13, and the absence of the Results Report for fiscal year 2012-13

As part of the performance system, each government agency must prepare annual execution plans that include the objectives to be met and the means to achieve them.

The OGP is responsible for the preparation of all regulations or guides necessary for the implementation of *Public Law 236-2010.* For this reason, it must advice and ensure compliance with the requirements of the *Law*, by each agency. As a part of its duty, the OGP issued *Circular Letter 97-12*[44], which establishes the guidelines for the preparation and submittal of the indicated documents.

The Department prepared the *Strategic Plan 2011-18* (Strategic Plan) and the *Annual Execution Plan 2012-13* (Execution Plan). Within the Department, each division submits its goals, objectives, activities and related information to the Division of Strategic Planning, where it is compiled and organized for the preparation of the aforementioned plans. Among these divisions is the Division of Immunization.

[44] See footnote 27.

In the *Strategic* Plan[45], the Division established 3 strategic goals, eight strategic objectives, 8 performance goals, and 9 activities. In the Execution Plan, it established 4 strategic goals, 10 strategic objectives, 10 performance goals and 11 activities.

Our examination of the Division's performance system revealed the following:

a. The Division's Strategic Plan, for the 2011-18 period, does not comply in its entirety with the requirements, because it lacked:
    - Quantifiable and measurable results or goals for the eight strategic objectives
    - A description of how the proposed goals and objectives would be reached as well as detail of the processes, skills, human resources and other resources necessary to accomplish those goals and objectives.
    - An analysis of how the goals included in the Execution Plan relate to the General goals of the Strategic Plan.
    - A description of the evaluation criteria of the program used to establish and review the general goals and objectives, as well as a calendar of the future evaluations of the program. In it, the frequency with which each goal and objective will be evaluated must be established.

b. The Execution Plan for the Division was not properly prepared, due to:
    - Strategic Goal 4 of said plan was not included in the strategic plan.
    - For the 4 strategic goals (100%), 10 strategic objectives (100%) and 9 of the 11 activities (82%), goals were not defined which allow measuring their performance.

[45] The same is included in the Strategic Plan of the Department, which can be accessed through the Internet page: www2.pr.gov/agencias/ogp/Pages/Planes-Estrategicos.aspx.

- For 6 of the 10 performance goals (60%) and 1 of 2 activities (50%) for which goals were defined, the goals are neither quantifiable nor measurable.
- Performance indicators to measure and evaluate the results, as well as the levels of service of the Division, were not included.
- It lacks reference data to compare the actual performance of the Division to the established performance goals.
- The metrics or other measuring tools to validate and verify the data compiled for the 4 strategic goals, 10 strategic objectives and 10 performance goals were not established.
- The frequency with which each activity of the Division included in the plan must be evaluated was not established.

c. A report of results for fiscal year 2012-13 as required by *Law 236-2010* and *Circular Letter 97-12 was not prepared.*

Criteria

The aforementioned situations are contrary to the requirements of *Law 236-2010* and *Circular Letter 97-12.*

Effects

The aforementioned situations did not permit the Division to set up a performance system that provides the tools to measure the efficiency and efficacy of its services; promote the accomplishment of its objectives to optimize its operation and government transparency; or improve the quality of services to the citizenry.

Nor do they allow the OMB to comply with *Law 236-2010* and *Administrative Order No. 147-14* from December 29, 2014, to publish the results to foster accountability. [section c.]

Comments from Management

See the comments from the Secretary of Health at the end of **Result 2.**

In the letter from the Executive Director of the OGP, he indicated, among other things, the following:

[...] the preparation and development of these documents is an obligation which the Law delegates on each agency, which can request advise from the OGP, if deemed necessary. However, our records do not show that the Department of Health requested advise from the OGP in the process of preparing their documents. [sic]

We considered the allegations from the Executive Director of the OGP, but we determined that the **Observation** prevails. This is so because we understand that the OGP must ensure the strategic plans, the execution plans and the results reports sent by the agencies comply with the requirements established in *Law 236-2010* and in *Circular Letter 97-12.* Further, because it is the government entity with very specialized knowledge on the subject, it must establish a program of guidelines and training for the government entities regarding the correct preparation of said documents.

See Recommendations 4, 5 and 14.

Observation 5 – Deficiencies related to the regulation approved for accountability, and forms that do not allow compliance with public policy

Our examination of the implementation of *Law 236-2010* revealed the following:

a. The regulations approved by the OGP do not establish:
    1) A procedure for review or audit of the documents remitted by the agencies where it is determined if they comply with the established criteria, before their publication.
    2) The components of the strategic and execution plans or annual work which will be evaluated in terms of efficiency, and which will be evaluated in terms of efficacy.

b. *Law 236-2010* and *Circular Letter Number 97-12* state that the results reports must describe the effectiveness and efficacy in the accomplishment of the objectives. This is not in agreement with the aforementioned public policy in said documents, which states that the objectives must be directed to determine the efficiency and efficacy of the services.

c. The models prepared by the OGP for compliance with the regulation, in force since January 30, 2015, do not allow for adequate accountability or the measurement of results since:

   1) The model for the Strategic Plan does not include the space for the performance indicator that must be utilized to measure the execution in the strategic goals and in the strategic objectives. Nor does it include an alternative document that includes said information.

   2) The model for the Execution Plan does not indicate that every year a performance goal that measures the progress of the strategic goal must be established, nor the performance indicators to measure each of the elements. Furthermore, erroneously, it joins the activities/effort and the performance indicators. The activities/efforts must be actions by the Agency to comply with its goals and objectives. While the performance indicators are tools that are used for the measurement of the achievement of the goals, objectives and activities in terms of efficiency and efficacy.

   3) The model for the Results Report does not set up a section to report the results for each strategic goal, strategic objective and efforts/activities.

Criteria

The situation discussed in **section a.1)** is contrary Article 8 of *Law 236-2010*, which authorizes the OGP to prepare all the regulations or guides necessary for its implementation.

The situations discussed in that **sections a.2), b. and c.** are contrary to Article 2 of *Law 236-2010.*

Effects

The aforementioned situations do not allow the agencies to set up a system of accountability that provides the tools to measure the efficiency and efficacy of their execution. Neither do they permit the promotion of the accomplishment of the objectives to optimize their operation, government transparency and to improve the quality of the services to the citizenry.

Further, the situation discussed in **section a.1)** does not allow the adequate oversight nor promotes the confidence of the sectors interested in the government operation.

Comments from Management

In the letter from the Executive Director of the OGP, he indicated, among other things, the following:

> [...] our agency issued Circular Letter 97-2012, which provides for: the preparation of Strategic Plans, including description (1.1), elements that must be included (1.1.2) and duration (1.1.3); the preparation of Annual Execution Plans, [...]; the preparation of Results Reports, [...]; and Guidance about formatting for the submission of the annual execution plans [...], among other elements. Consequently, with respect to the OGP, adequate and sufficient norms have been provided, as far as our agency is concerned, through Circular Letter 97-2012. [sic]
>
> [...] we reiterate the advising function of our agency in diverse management aspects to the government agencies. However, each entity is responsible for the internal training of its human resources and for compliance with its ministerial duties. In the case of State Department of Health, the agency has an Office of Planning and Statistics, which must pass judgment for the evaluation of the working plans of each of its operational divisions.

We considered the allegations by the Executive Director of the OGP, but we determined that the **Observation** prevails. This, because we understand that there are deficiencies regarding the regulation and the forms and they hamper compliance of the established public policy regarding accountability and governmental transparency.

See Recommendations 15 and 16.

Strategic Plan - document in which management lays out what its strategy will be for a given period. The plan must be quantitative, as it describes how to reach goals and the strategies to be followed. It should also be temporal, since it indicates the deadlines the agency has for meeting those goals.

Observation 6 – Deficiencies related to the execution of two strategic goals and one activity included in the Annual Execution Plan 2012-13, and the absence of information needed to measure performance and accountability.

Law 236-2010 and *Circular Letter 97-12* require that, for the division to be able to optimize its operation and service, it must implement what is established in its Strategic Plan and its annual execution plans. Further, it must prepare a results report, which contains, among other things, the goals and objectives reached and an explanation and description of those that were not reached.

Our auditors evaluated the Division's Annual Execution Plan 2012-13. However, because the Department did not present its results report for fiscal year 2012-13, they asked the Division's Director to certify the results for each of the goals, objectives and activities. Further, they interviewed the employees and staff of the division and requested additional evidence to corroborate the results, to evaluate the progress in the coverage of the four strategic goals.

The lack of quantifiable and measurable indicators and goals **[See Result 2]** did not allow us to evaluate the efficacy and the efficiency of the Division. For that reason the effectiviness on the execution was evaluated.

Our evaluation of the execution of the Division revealed that:

a. The performance system allowed us to evaluate 4 strategic goals, 3 performance goals and 1 activity. From these, we determined that the Division was not effective in the execution of adequate progress in the coverage and in carrying out educational campaigns.

b. The Division's performance system did not allow us to evaluate its execution in terms of efficacy because we were not provided evidence or information about it.

Criteria

The situation discussed in **section a.** is contrary to what is established in the *Annual Execution Plan 2012-13* and in the *Strategic Plan 2011-2018.*

The situation discussed in **section b.** is contrary to Article 6 of *Law 236-2010* and to Subparagraph 1.3 of *Circular Letter 97-12.* Further, it is also contrary to the norm of sound management that the results reported by the Division in compliance with its strategic plans and annual execution plans, must be corroborated by an entity outside the operation.

Effects

The indicated results did not allow the division to:

- Establish a performance system in accordance with *Law 236-2010.*
- Find out the results of its operations to be able to establish measures, which allow it to accomplish its goals and objectives, and improve its efficiency.
- Report back on its performance, through the publication of the results.

Furthermore, it did not allow our auditors to determine whether the Division was effective and efficient in the fulfillment of its *Annual Execution Plan 2012-13.*

Comments from Management

In the letter from the Secretary of Health, she indicated, among other things, that even though the situations that prevent pediatricians from resuming vaccination have not been evaluated in their entirety **[Section b.]**, there has been information gathered on the most important factor, which is the economic.

See Recommendation 6.

SOCIAL CONSEQUENCES

The results and observations that are presented in this *Report* can have the following social consequences:

1. Not dealing with the issues that affect accessibility to immunization services for children and adolescents under 18 in the private sector, can cause them not to reach the recommended immunization levels and, consequently, increase the incidence of certain illnesses preventable by vaccines and increase the medical costs associated with them.
2. Without monitoring and taking action regarding the decreasing number of pediatricians, they can become scarce in Puerto Rico, and the specialty service that they provide, which is necessary for the development and health of children and adolescents, could be affected.
3. If the insurance companies do not cover immunization services which they are required to cover free of co-payments, people with private health insurance are forced to obtain them in centers sponsored by the state and federal government, which could cause the loss of those funds and the unjust enrichment of insurers.
4. The absence of strict oversight of the institutions that must register the immunization information in the *PRIR* makes it difficult to obtain complete data, and to establish the necessary strategies to protect the population through this mechanism.
5. If statistics about homeschooled children are not maintained, it is difficult for the Government to set up follow-up of those minors and to set up the strategies to ensure that the family, as well as the State, meet their obligations, as established in Articles 5 and 7 of *Public Law 246-2011, Child Safety, Wefare and Protection Act.*

6. Not setting up a system of accountability and governmental transparency prevents improvement of the execution of government programs. Further, it could lead to the invested resources not having useful results.
7. Not establishing a procedure for the evaluation or review of the documents submitted by the agencies to the OGP makes it impossible to determine whether the information furnished by them reflects the results of their operations, and whether it presents the reality about the execution of the agency or the corresponding program. These situations must be dealt with in order to encourage Government entities to promote measures directed towards specific ends, where they labor to improve the execution of government and the services to the citizenry.

RECOMMENDATIONS

To the Secretary of Health

1. Promote strategies that encourage participation by doctors in providing vaccination services. Further, monitor access to those services in the private sector. **[Result 1]**
2. Investigate the situation related to the certificates of limited coverage issued by the health plans in order to take the appropriate measures, among them, to evaluate if it is appropriate to recover the funds for the servicers which they should have provided. **[Result 1 and Observation 1]**
3. Revise *Regulation 1968* so that it is updated in accordance with *Public Law No. 25* and with the organizational, administrative and operational changes in the Department. **[Observation 2]**
4. See that the strategic plans and the annual execution plans are prepared in accordance with what is established in *Law 236-2010* and in *Circular Letter 97-12,* and that they provide accountability and the adequate measurement of their execution. **[Result 2 and Observation 4-a. and b.]**
5. Ensure that the Results Report is prepared and remitted annually to the OGP. **[Observation 4-c.)]**
6. Establish the necessary measures so that the performance system of the Division of Immunization contains the necessary elements that

allow the evaluation of its execution in terms of efficacy. Among these, strategies to improve and optimize the execution of the Division in the coverage of immunization and to adequately document the results reached and maintain evidence of the actions undertaken. **{Result 3 and Observation 6]**

To the Puerto Rico Insurance Commissioner

7. Audit, in a timely fashion, situations that affect services for patients, caused by non-compliance by private insurers, and which may cause the loss of government funding. **[Result 1 and Observation 1]**

To the Secretary of Education

8. See that *Regulation 1968* is revised so that it is updated in accordance with *Public Law No. 25* and with the organizational, administrative and operational changes in the Department. **[Observation 2]**
9. Exercise effective supervision over the functions of the school directors to ensure that the information on students' immunization is included in the *PRIR*. **[Observation 3]**

To the Secretary of the Family

10. See that *Regulation 1968* is revised so that it is updated in accordance with *Public Law No. 25* and with the organizational, administrative and operational changes in the Department. **[Observation 2]**
11. Exercise effective overview the administration of day care centers to ensure the information on children's immunization is included in the *PRIR*. **[Observation 3]**

To the Administrator, Administration for Child Care and Development

12. Exercise effective overview over the management of Head Start and Child Care centers that receive funding through ACUDEN, to ensure that information on children's immunization is included in the *PRIR*. **[Observation 3]**

To the President of the Puerto Rico Council on Education

13. Exercise effective oversight of the management of private schools and public and private universities to ensure that students' information on immunization is included in the *PRIR*. **[Observation 3]**

To the Director of the Office of Management and Budget

14. Set up an orientation and training program for the government agencies regarding the correct preparation of strategic plans, execution plans and results reports to ensure they comply with the requirements established in *Law 236-2010* and in *Circular Letter 97-12.* **[Result 2 and Observation 4]**
15. Review the regulation and the approved forms for compliance with *Law 236-2010,* and ensure that they include:
    a. Procedures for the review or audit of the documents remitted by the agencies. **[Observation 5-a.1)]**
    b. The explanation of the elements in the strategic and annual plans which must be evaluated in terms of efficacy or efficiency, or both. **[Observation 5-a.2)]**
    c. Elements that allow the measurement of results of the execution of the programs and the agencies, and accountability. **[Observation 5-c.]**
16. Promote the revision of Article 6, subparagraph 4 of *Law 236-2010* and correct Section 1.3.4(b) of *Circular Letter 97-12* so that it is drafted in accordance with the public policy in that *Law.* **[Observation 5-b.]**

ACKNOWLEDGMENT

To the staff and employees of the Department of Health, the Puerto Rico Institute of Statistics, and the OCS; to the members of the College of Medical Surgeons and the Association of Academic Psychiatrists; and to the members of the Reference Panel; we thank them for the cooperation they lent us during our audit.

By: (Handwritten) Office of the Comptroller

APPENDIX 1

DEPARTMENT OF HEALTH

IMMUNIZATIONS DIVISION

MEMBERS OF THE REFERENCE PANEL

Name		Academic Credentials	Position
Dr. Mario Marazzi Santiago	2002	Doctorate in Economics Cornell University	Executive Director Puerto Rico Statistics Institute 2007 - Present
	1998	Masters in Economics London School of Economics	
	1997	Bachelor in Economics Harvard University	
Dr. José F. Cordero Cordero[46]	1979	Master in Public Health Professor Harvard University	Graduate School of Public Health
	1975-77	Specialty in Genetics Pediatric Department Massachusetts General Hospital	Director Institute for Genomics and Public Health, University of Puerto Rico, Health Science Campus, since 2006
	1973-75	Resident Department of Pediatrics Boston City Hospital	
	1973	Medical Degree School of Medicine of the University of Puerto Rico	
	1969	Bachelors in Biology University of Puerto Rico	
Dra. Palmira N. Ríos González[47]	1990	Doctorate in Sociology Yale University	Dean of Academic Affairs University of Puerto Rico, since 2015
	1975	Masters in Sociology and Caribbean Studies	
	1974	Bachelors in Sociology University of Puerto Rico	

[46] On the date of our audit, he served as Dean of the Graduate School of Public Health, University of Puerto Rico, Health Sciences Campus.

[47] On the date of our audit, she served as Dean of the Graduate School of Public Administration, University of Puerto Rico.

APPENDIX 2

DEPARTMENT OF HEALTH

DIVISION OF IMMUNIZATION

PRINCIPAL STAFF OF THE AGENCY

DURING THE AUDITED PERIOD

NAME	POST	PERIOD FROM	PERIOD TO
Hon. Ana C. Ríus Armendáriz	Secretary	16 Sep. 13	28 Feb. 15
Dr. Francisco Joglar Pesquera	Secretary	2 Jan. 13	13 Sep. 13
Dr. Lorenzo González Feliciano	"	1 Jan. 11	31 Dec. 12
Ricardo Torres Muñoz	Assistant Secretary of Family Health and Integrated Services	5 Nov. 13	28 Feb. 15
Dr. Raúl Castellano Bran	Interim Deputy Secretary of Family Health and Integrated Services[48]	1 Jan. 13	4 Nov. 13
Maritza Espada Méndez	Deputy Secretary of Family	16 Aug. 12	31 Dec. 12
Margaret Wolfe	"	1 Jan. 11	29 Jun. 12
Plan. Eddy Sánchez Hernández	Assistant Secretary of Planning	1 Jan. 13	28 Feb. 15
Mr. José A. Vázquez Román	"	1 Jan. 11	31 Dec. 12
Dr. Ángel M. Rivera García	Director of the Division of Immunization	1 Jan. 11	28 Feb. 15

[48] This post was vacant from June 30, to August 15, 2012.

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