



Republic of the Philippines  
Department of Health  
**OFFICE OF THE SECRETARY**

NOV 23 2015

**ADMINISTRATIVE ORDER**  
No. 2015 - 0049

**SUBJECT: Rules and Regulations Governing the Antimicrobial Resistance Surveillance Program Accreditation of Bacteriology Laboratories in the Philippines for the PhilHealth Reimbursement of Select Antibiotics in the Philippine National Drug Formulary**

**I. RATIONALE**

Republic Act No. 3720 as amended by Executive Order 175, series of 1987 mandates that the government through the Department of Health should adopt measures to ensure rational use of drugs and devices. Hence, the Philippine National Drug Policy (PNDP) included the promotion of rational use of drugs as one of its five pillars. Rational drug use refers to a carefully considered pattern of behavior on the part of the prescriber and the consumer. This focuses on limiting the use of medications in conditions with clear and valid indications. This also centers on use of the the most necessary and scientifically proven efficacious drugs. Efforts to implement rational antibiotic use was the overarching aim in the creation of the Antimicrobial Resistance Surveillance Program (ARSP) thru the Department Order 339J in 1988. This issuance mandated the program to initiate a national surveillance to identify trends of resistance in bacterial pathogens of public health importance to provide the necessary critical information that can be used as basis for the efforts of the government to promote rational use of antimicrobials.

The critical surveillance data from the program necessitates ensuring that quality microbiological test results are generated by the member sentinel sites of the program. With the designation of the Antimicrobial Resistance Surveillance Reference Laboratory as the reference laboratory for antimicrobial resistance (DO 393-E s 2000), this then included provision of quality assurance programs for bacteriology laboratories as one of its mandates. Hence, scope of the quality assurance program included all bacteriology laboratories in the country when the ARSP partnered with PhilHealth in a scheme that allowed reimbursements for select antibiotics for hospitals with ARSP accredited laboratories (PhilHealth Circular 15 s 2006). This quality assurance program for ARSP Accreditation of Bacteriology Laboratories aimed to ensure that bacteriology laboratories provide only reliable quality test results which can serve as important basis for rational use of antibiotics for treatment of infectious diseases. These quality laboratory data will allow clinicians to select the most effective and appropriate antibiotic regimens for treatment of infectious diseases at the lowest cost to the patients in effect ensuring only drugs that are appropriate, necessary and inline with current standards of care are used for patient care and for reimbursement by PhilHealth. Furthermore, improving rational antibiotic use contributes enormously in minimizing emergence of antimicrobial resistant microorganisms by preventing inappropriate use and abuse of antibiotics.

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## **II. OBJECTIVES**

This Order is promulgated to prescribe the minimum standards for bacteriology laboratories to ensure quality microbiology results are used as basis in the selection of antimicrobials for the treatment of bacterial infections thereby promoting rational antibiotic use and the reimbursement by the Philippine Insurance Corporation only of appropriately used antibiotics.

## **III. SCOPE AND COVERAGE**

The Administrative Order shall apply to all individuals, agencies, partnerships or corporations that operate tertiary hospitals with bacteriology laboratories in the Philippines applying for reimbursement of select antibiotics in the Philippine National Drug Formulary and performing microbiological testing and analysis of samples from humans.

## **IV. DEFINITION OF TERMS**

A. Antimicrobial Resistance Surveillance Program – a program of the Department of Health which monitors the current levels and developing trends of antibiotic resistance of aerobic bacteria of public health importance and performs reference laboratory functions related to antimicrobial resistance, with the goal being to utilize such data as basis for rational antibiotic use

B. Bacteriology laboratory – a laboratory which deals with culture, isolation, identification, susceptibility testing of bacterial pathogens from human samples

C. Accreditation – the act of granting recognition to an institution which maintains suitable standards and specific requirements set by an official review board

D. Restricted antibiotics – list of antibiotics to be reimbursable to hospitals by PhilHealth once a bacteriology laboratory is accredited by the ARSP

## **V. GENERAL GUIDELINES**

1. Reimbursement of restricted antibiotics from the Philippine National Drug Formulary will be awarded only to hospitals with ARSP Bacteriology Laboratory Accreditation. The list of restricted antibiotics shall be updated periodically by the PhilHealth upon the recommendation of the ARSP based on the national antimicrobial resistance data.

2. The Antimicrobial Resistance Surveillance Reference Laboratory shall implement a quality assurance scheme for the ARSP Bacteriology Laboratory Accreditation annually with accreditation validity good for 3 years.

3. Bacteriology laboratories are to comply with the minimum requirements set in the AO 2007-0027 Revised Rules and Regulations Governing the Licensure and Regulation of Clinical Laboratories in the Philippines unless superseded by a more current issuance.

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## VI. PROCEDURAL GUIDELINES

A. Procedure for registration for the ARSP Bacteriology Laboratory Accreditation shall be as prescribed by RITM ARSRL issuance which can be downloaded from the official website of RITM ([www.ritm.gov.ph](http://www.ritm.gov.ph)), ARSP or another web portal recognized by ARSP.

### B. Roles and Responsibilities

1. PhilHealth shall perform, with due diligence and efficiency the following undertakings:
  - a. Provide a liaison group thru its Quality Assurance Group (QG) as identified by PhilHealth that would coordinate with the Department of Health and the Research Institute for Tropical Medicine to provide inputs and feedback, and facilitate obtainment from the management of any policy or program decisions related to the assistance mentioned hereafter; and
  - b. Fully support the ARSP by issuing appropriate Circular(s) for its implementation;
2. Department of Health shall perform, with due diligence and efficiency, the following undertakings:
  - a. Provide a liaison group that would closely coordinate with PhilHealth and RITM to provide inputs and feedback, and facilitate obtainment from the management of any policy or program decisions related to the provision of technical assistance mentioned hereafter;
  - b. Provide adequate budget to be allotted and released for maintenance and other operating expenses of RITM for the ARSP;
  - c. Develop and/or issue relevant policies related to the program to ensure that laboratories of tertiary hospitals (Level 2 and 3) conform to international and local standards and technical requirements; and
  - d. Authorizes the RITM ARSRL to collect fees related to the ARSP Bacteriology Laboratory Accreditation.
3. The Antimicrobial Resistance Surveillance Reference Laboratory of the Research Institute for Tropical Medicine shall perform, with due diligence and efficiency, the following undertakings:
  - a. Provide a liaison group that would closely coordinate with PhilHealth and DOH to provide inputs and feedback, and facilitate obtainment from the management of any policy or program decisions related to the provision of technical assistance mentioned hereafter;
  - b. Provide training to laboratories of tertiary hospitals (Level 2 and 3) on ARSP accreditation standards and monitoring procedures;
  - c. Provide the reference laboratory technical standards and guidelines for the overall operations of the ARSP;
  - d. Provide technical advice to PhilHealth in matters relating to accreditation of bacteriology laboratories in the Philippines;
  - e. Undertake annual accreditation of bacteriology laboratories in the Philippines;
  - f. Implement an External Quality Assurance Program in bacteriology laboratories for ARSP Bacteriology Laboratory Accreditation by performing the following:
    - 1) Prepare and distribute unknown isolates under the External Quality Assurance Program for participating laboratories;

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- 2) Provide timely feedback and results of the unknowns to the participating laboratories;
  - 3) Inspect, monitor and provide feedback to laboratories of participating tertiary (Level 2 and 3) hospitals following the guidelines drawn by ARSP;
- g. Provide feedback to PhilHealth and DOH on results of laboratory proficiency tests and inspections;
- h. Provide PhilHealth and the Department of Health the list of accredited laboratories on an annual basis.

#### **VII. SCHEDULE OF FEES**

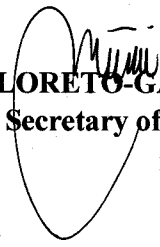
1. A non-refundable registration fee of P7,000.00 shall be charged for each applicant to cover the application fee (Php 1,500.00) and dispatch of unknowns (Php 5,500.00).
2. An inspection fee to cover for travel, meals and accommodations for 2 inspectors is charged to participating laboratories that passed the proficiency testing based on current prevailing standards.
3. All fees/ checks shall be paid directly to the RITM Landbank account and shall follow the current DOH prescribed schedule of fees. A copy of the deposit slip should accompany the requirements for registration. A RITM official receipt will be issued to registered applicant laboratory upon receipt of the deposit slip copy thru courier.

#### **VIII. SEPARABILITY CLAUSE**

If any provision of this order is declared unauthorized or rendered invalid by any court of law or competent authority, those provisions not affected thereby shall remain valid and effective.

#### **IX. EFFECTIVITY**

This order shall take effect fifteen (15) days after publication to an official gazette or a newspaper of general circulation.

  
**JANETTE LORETO-GARIN, MD, MBA-H**  
**Secretary of Health**