



Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

APR 30 2021

ADMINISTRATIVE
ORDER No. 2021 - 0033

SUBJECT: Revised 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 Formulary

I. RATIONALE

DOH Administrative Order (AO). No. 2015-0049 "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", was issued to provide guidelines in the operations of the accreditation of bacteriology laboratories by the Antimicrobial Resistance Surveillance Program (ARSP). The Order was amended by AO 2015-0049-A to align terminologies with the DOH A.O. No. 2007-0027 Revised Rules and Regulations Governing the Licensure and Regulation of Clinical Laboratories in the Philippines. Additional changes had been prescribed by the Antimicrobial Resistance Surveillance Reference Laboratory (ARSRL) to update the guidelines in order to improve the processes of ARSP Accreditation and ensure quality service delivery to applying laboratories. This Order is hereby issued to update the requirements of the existing Order and align it with the Republic Act No. 11223, otherwise known as "Universal Health Care Act" and its Implementing Rules and Regulations (IRR).

II. OBJECTIVES

This Order is promulgated to provide minimum standards in the process of accreditation of tertiary clinical laboratories by the DOH Antimicrobial Resistance Surveillance Program for the use of restricted antibiotics listed in the Philippine National Formulary (PNF).

III. SCOPE AND COVERAGE

The Administrative Order shall apply to DOH and all its units, including the Bangsamoro Autonomous Region in Muslim Mindanao (BARMM) subject to the applicable provisions of RA 11054 or the "Bangsamoro Organic Law" and subsequent rules and policies issued by the Bangsamoro government, all individuals, agencies, partnerships or corporations that operate tertiary clinical laboratories in the Philippines, performing microbiological testing and analysis of samples from humans and applying for reimbursement of select antibiotics in the PNF.

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IV. DEFINITION OF TERMS

- A. *Accreditation* refers to the act of granting recognition to an institution which maintains suitable standards and specific requirements set by an official review board.
- B. *Antimicrobial Resistance Surveillance Program (ARSP)* refers to the 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 of utilizing such data as basis for rational antibiotic use.
- C. *Antimicrobial Resistance Surveillance Reference Laboratory (ARSRL)* refers to the department under the Research Institute for Tropical Medicine which serve as the reference laboratory and coordinating unit of the ARSP.
- D. *Bacteriology laboratory* refers to a laboratory which deals with culture, isolation, identification, susceptibility testing of bacterial pathogens from human samples.
- E. *Restricted antibiotics* refers to a list of antimicrobials prescribed under the latest edition of the PNF to be reimbursed to hospitals by PhilHealth once a bacteriology laboratory is accredited by the ARSP.
- F. *Tertiary clinical laboratory* refers to a clinical laboratory, regardless of its classification by ownership, function, and institutional character, which provides minimum service capabilities for the following: routine and special hematology including coagulation studies, blood typing* and cross matching*, qualitative and quantitative platelet count determination, routine urinalysis and fecalysis, routine and special chemistry, serology and immunology, and microbiology including potassium hydroxide (KOH) testing* and culture and sensitivity. (*for hospital-based laboratories only) qualitative and quantitative platelet determination, routine urinalysis and fecalysis, routine clinical and special chemistry, cross matching*, potassium hydroxide (KOH) testing*, blood typing*, immunology, and microbiology-culture and sensitivity. (*for hospital based laboratories only).

V. GENERAL GUIDELINES

- A. Reimbursement of restricted antibiotics from the latest edition of the PNF shall be allowed for institutions with tertiary clinical laboratories with ARSP Bacteriology Laboratory Accreditation. The list of restricted antibiotics shall be updated periodically by PhilHealth upon the recommendation of the ARSP based on the above mentioned reference.
- B. The Antimicrobial Resistance Surveillance Reference Laboratory shall implement an annual quality assurance program for the ARSP Bacteriology Laboratory Accreditation. The length of accreditation validity is three (3) years. The length of accreditation validity to be offered to new applicants may be adjusted, in concurrence with PhilHealth.
- C. Tertiary clinical laboratories shall 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.

VI. IMPLEMENTING GUIDELINES

A. Registration Process

1. Procedure for registration for the ARSP Bacteriology Laboratory Accreditation shall be prescribed by RITM ARSRL issuance which can be downloaded from the official website of RITM (www.ritm.gov.ph), ARSP (www.arsp.com.ph) or another web portal recognized by ARSP.
2. Applicants who have successfully registered for ARSP Accreditation will receive an official acknowledgement letter. This document shall serve as documentary evidence to PhilHealth inspectors of the laboratory's pursuance of ARSP accreditation.

B. ARSP Accreditation Process

The institution applying for ARSP accreditation shall undergo and is required to pass two (2) phases for successful accreditation.

1. Proficiency Test: The applicant laboratory shall receive from ARSRL- RITM unknown bacterial isolates for identification. Worksheets shall be provided together with the analytes to be sent back to the ARSRL at a specified deadline. Laboratories are required to pass this phase to be able to proceed to the second phase which is the inspection.
2. Inspection: ARSRL staff shall visit the laboratories who passed the proficiency test and assess the current practices and infrastructure using a standard tool adapted from WHO Laboratory Assessment Guide. All laboratories that pass the inspection shall be given the Accreditation.

VII. SCHEDULE OF FEES

- A. A non-refundable application fee shall be charged for each applicant to cover the processing and dispatch of unknowns, amount of which shall be based on current prevailing rates of reagents, courier, and clearance fees, published at the ARSP website (www.arsp.com.ph) and the RITM website (www.ritm.gov.ph). The application fee shall be subject to change without prior notice.
- B. Expenses incurred during inspection which includes travel, per diem, and accommodations for two (2) inspectors and a driver (where applicable) shall be shouldered by participating laboratories that passed the proficiency testing based on current prevailing standards.
- C. The application fee shall be paid directly to the RITM Landbank account and shall follow the current prescribed schedule of fees. A copy of the deposit slip should accompany the requirements for registration. An RITM official receipt shall be sent to the registered applicant laboratory together with the dispatch of proficiency test samples through courier.

VIII. ROLES AND RESPONSIBILITIES

- A. Research Institute for Tropical Medicine- Antimicrobial Resistance Surveillance Reference Laboratory shall:
 1. Coordinate with PhilHealth and DOH-Health Policy Development and

Planning Bureau for inputs and feedback on any policies and decisions related to the operation of the accreditation scheme.

2. Provide technical advice to PhilHealth in matters relating to accreditation of bacteriology laboratories in the Philippines;
3. Undertake annual accreditation of bacteriology laboratories in the Philippines;
4. Implement the ARSP Bacteriology Laboratory Accreditation by performing the following:
 - i. Prepare and distribute unknown isolates under the External Quality Assurance Program for participating laboratories;
 - ii. Provide timely feedback and results of the unknowns to the participating laboratories;
 - iii. Inspect, monitor and provide feedback to participating tertiary clinical laboratories following the guidelines drawn by ARSP;
 - iv. Provide feedback to PhilHealth and DOH on results of laboratory proficiency tests and inspections;
 - v. Provide PhilHealth and the Department of Health the list of accredited laboratories on an annual basis.

B. Philippine Health Insurance Corporation (PHIC)

1. Provide a liaison group thru its Quality Assurance Group (QAG) that would coordinate with the Department of Health and the Research Institute for Tropical Medicine for inputs and feedback;
2. Facilitate obtainment of any policy or program decisions required to implement the accreditation scheme; and
3. Fully support the ARSP by issuing appropriate Circular(s) for implementation.

C. Department of Health - Pharmaceutical Division

1. Coordinate with PhilHealth and RITM on inputs and feedback, and provision of information for policy and program management and decision-making process.
2. Develop and/or issue relevant policies related to the program to ensure that tertiary clinical laboratories conform to international and local standards and technical requirements.

IX. 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 in effect.

X. REPEALING CLAUSE

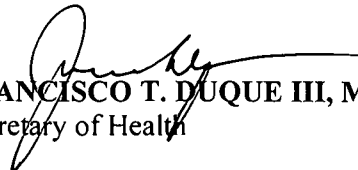
All rules and regulations stipulated in DOH A.O. 2015-0049 *Rules and Regulations Governing the Antimicrobial Resistance Surveillance Program Accreditation of Bacteriology Laboratories in the Philippines for the PhilHealth Reimbursement of Select Antibiotics in the Philippine National Drug Formulary* and DOH A.O. 2015-0049-A *Amendment to Administrative Order No. 2015-0049 entitled "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"* are hereby repealed. All other issuances inconsistent or contrary to the provisions of this Order are hereby amended and modified accordingly.

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XI. EFFECTIVITY

This Order shall take effect after fifteen (15) days following its publication in a newspaper of general circulation, posting in the official DOH website (www.doh.gov.ph), RITM Website (www.ritm.gov.ph) and upon filing with the University of the Philippines Law Center of three (3) certified copies of this Order.


FRANCISCO T. DUQUE III, MD, MSc
Secretary of Health

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