

Bulgarian National Audit Office

PLANNING, CONDUCTING AND PRESENTING PERFORMANCE AUDITS WITH THE HELP OF ISSAI 3000 AND ISSAI 3100 IN THE FIELD OF HEALTHCARE

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PERFORMANCE AUDITS IN THE FIELD OF HEALTHCARE

- According to the new National Audit Office Act effective January 2011 the Bulgarian NAO "shall exercise control over the implementation of the budget and of other public funds and activities in accordance with this Act and the internationally accepted auditing standards", incl. ISSAIs (Art. 1, para 2).
- As per Art. 20 of the Act the President published the internationally accepted auditing standards on the National Audit Office website.
- We hereby present two performance audits in the healthcare sector carried out in the first half of 2012 which are among the first audits in the frames of the new act.



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PERFORMANCE AUDITS IN THE FIELD OF HEALTHCARE (2)

- **Regulation of Pharmaceutical Pricing and Reimbursement**
 - audited period from 01.01.2008 to 31.12.2011;
 - audit assigned by the Parliament;
 hereinafter referred as "audit of pharmaceutical pricing";
- **Implementation of activities of the Ministry of Health on providing treatment of patients with chronic renal insufficiency by non-renal purification methods of blood**
 - audited period from 01.01.2009 to 30.06.2011;
 hereinafter referred as "audit of dialysis".



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PLANNING (1)


Strategic planning included:

- Determining the potential audit areas;
- Establishing the selection criteria – added value, problem areas, risks;

(ISSAI 3000)
The field of healthcare has been determined as a priority in performance audits.

Main steps of the planning of our audits encompassed:

- Defining the specific issue to be studied and the audit objectives;
- Developing the scope and the design of the audit;
- Determining the quality assurance, the timetable, and the resources (ISSAI 3000).


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PLANNING (2)

Main questions and specific questions of our audits:
Audit of pharmaceutical pricing

- Is the process of regulation of pharmaceutical pricing and reimbursement effective/efficient?
- Are adequate conditions created for successful implementation of the process of regulation of pharmaceutical pricing and reimbursement?
- Is an effective mechanism provided for regulation of pharmaceutical pricing and reimbursement?

Audit of dialysis


- Is the implementation of activities of the Ministry of Health on providing treatment of patients with chronic renal insufficiency effective?
- Is the financing of the activities secured?
- Are the necessary pharmaceuticals, medical devices and technical equipment provided?
- Are effective the dialysis treatment and control effected?


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PLANNING (3)


- The objectives of both audits are to provide the legislature and the government with an independent and objective assessment of the effective/efficient implementation of audited activities, to identify weaknesses and to give recommendations for improvement.
- On the basis of the understanding of the subject matter (pharmaceutical pricing and activities on dialysis treatment), assessment of inherent risks and control activities, the scope of both audits has been defined.
- Audit criteria and indicators have been defined.
- The matrix of planning contains audit questions, criteria and indicators, sources of audit evidence, general audit strategy, data collection methods, methods of analysis of data, limitations of the scope, expected findings.


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PLANNING (4)

- Result-oriented approach has been applied together with direct substantive testing.
- The audit team leader carries out day-to-day control over the work of team members.
- The audit team leader elaborates timetable and resources.
- Discussion with the auditee management on the audit scope, objectives, criteria and indicators.
(ISSAI 3000)
- All audit procedures at the stage of planning as well as at conducting, reporting and follow-up are duly documented.


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CONDUCTING THE AUDITS (1)

At the stage of implementation of the work plan in order to obtain sufficient and relevant audit evidence, to have well-grounded findings and make an objective assessment of effectiveness and efficiency of auditees' activities, we applied data collection techniques, some of which are as follows:

Audit of pharmaceutical pricing

- Questionnaires sent to all EU Member States on the systems of pricing and reimbursement of pharmaceuticals;
- Study of Reports on Pricing and Reimbursement Information by the European Commission, DG Health and Consumers (general and by countries);
- External experts;
- Direct substantive testing.


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CONDUCTING THE AUDITS (2)

Audit of dialysis

- On-the-spot checks in hospitals with dialysis departments (as per audit sample) together with Medical Audit Executive Agency as experts in the medical field of activities;
- Questionnaires and interviews for obtaining opinion of all stakeholders:
 - National Dialysis Adviser;
 - Regional Health Inspectorates;
 - Management of hospitals;
 - Heads of Dialysis departments in hospitals;
 - Patients' Organisations;
 - Patients at Dialysis departments in hospitals.

(ISSAIs 3000 and 3100)

Findings, conclusions and recommendations have been discussed with auditees.


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CONDUCTING THE AUDITS (3)

Conclusions

Audit of pharmaceutical pricing

- The process of regulation of pharmaceutical pricing and reimbursement is legally provided. Strategic documents have been approved, except for the document "National Pharmaceutical Policy" during the audited period.
- The process of regulation of pharmaceutical pricing and reimbursement is not enough effective and efficient and undertaking of adequate measures for improvement is necessary.
- Recommendations for improvement of audited processes are given to the Council of Ministers, Minister of Health and Governor of the National Health Insurance Fund.


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CONDUCTING THE AUDITS (4)

Conclusions

Audit of dialysis

- Activities of the Ministry of Health on treatment of patients with chronic renal insufficiency by non-renal purification methods of blood are legally provided.
- Insufficient financing, equipment and medical staff as well as deviations from the medical standard influence negatively the quality of dialysis treatment.
- Recommendations for improvement of audited activities are given to the Minister of Health and Governor of the National Health Insurance Fund.


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REPORTING


- Audit reports from both audits have been elaborated and approved by the President of the Bulgarian NAO.
- Audit reports with well-founded and objective information, analyses and assessments were well communicated to the auditees.

(ISSAI 3000)

- The audit report of dialysis treatment was sent to the prosecutor's office in relation to the possible abuse of budgetary funds earmarked for dialysis equipment.

(ISSAI 1240).

- Audit reports were published at the Bulgarian NAO web-site **(ISSAI 3000)**; the audit report of dialysis – with the exception of excerpts containing findings sent to the prosecutor's office.


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FOLLOW UP (1)

Follow-up audits were conducted for assessing the implementation of recommendations.

Audit of pharmaceutical pricing

- Out of 9 recommendations, one is fulfilled, 6 are in process of implementation, two are partially executed.
- As a result of the audit conducted, amendments to the applied legislation have been made and respectively to the practice of regulation of pharmaceutical pricing and reimbursement. A new entity has been created and charged with this process.
- Audit results were widely reflected by the media.



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FOLLOW UP (2)

Audit of dialysis

- Out of 7 recommendations, one is fulfilled, 6 are in process of implementation.
- As a result of the audit conducted, amendments to the applied legislation have been made, a mechanism for control of unabsorbed earmarked funds has been elaborated and analysis of the dialysis activities and equipment has been made.
- Audit results were widely reflected by the media.

(ISSAIs 3000, 3100)




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IN CONCLUSION ...

- We have used ISSAIs 3000 and 3100 in our audits in the field of healthcare as mentioned before and on that basis we came to well-grounded findings and conclusions. In addition, we also used ISSAI 1240. We achieved positive results and impact of our audits.
- As ISSAIs are more general, this year in the Bulgarian NAO a new Performance Audit Manual with detailed procedures has been introduced on the implementation of internationally accepted auditing standards and audit activity (according to the Bulgarian NAO Act). Currently, the Manual is being tested in our audits in process of implementation.
- In our opinion the use of ISSAIs is very helpful and definitely improves the quality of audit activities.




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Thank you for the attention!



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