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| **THE FRENCH REPUBLIC** | | |
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| Ministry of Solidarity and Health | | |
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**Order of 10 April 2021**

**amending the Order of 10 July 2020 setting out the organisational and operational health system measures necessary to deal with the COVID-19 epidemic in the context of the state of health emergency**

**NOR:**

**The Minister for Solidarity and Health,**

Having regard to Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services, and in particular Notification No;

Having regard to the Social Action and Family Code;

Having regard to the Public Health Code, in particular Article L3131-16 thereof;

Having regard to the Social Security Code;

Having regard to Law No 2020-734 of 17 June 2020 on various provisions relating to the health crisis, other urgent measures and the withdrawal of the United Kingdom from the European Union, as amended, in particular Article 23 thereof;

Having regard to Law No 2020-1379 of 14 November 2020 authorising the extension of the state of health emergency and laying down various measures for managing the health crisis, as amended;

Having regard to Decree No 2020-1257 of 14 October 2020 declaring the state of health emergency;

Having regard to Decree No 2020-1262 of 16 October 2020 prescribing the general measures necessary to deal with the COVID-19 epidemic in the context of the state of health emergency, as amended;

Having regard to Decree No 2020-1310 of 29 October 2020 prescribing the general measures necessary to deal with the COVID-19 epidemic in the context of the state of health emergency, as amended;

Having regard to the Order of 10 July 2020 prescribing the organisational and operational health system measures necessary to deal with the COVID-19 epidemic in the context of the state of health emergency, as amended;

Having regard to the opinion of the Board of the French National Authority for Health on the rapid antigenic detection of SARS-CoV-2 on nasal swabs (TDR, TROD and self-test) dated 15 March 2021;

Whereas army hospitals care for patients suffering from COVID-19 under the same conditions as health establishments and, as such, bear expenses for benefits not included in the package of care which require additional charges;

Whereas vaccination against SARS-CoV-2 is essential in order to contain the epidemic and whereas the particular conditions for the implementation of such vaccination, in which army hospitals participate, require, as is the case for health establishments, provision for specific remuneration for such hospitals;

Whereas it is necessary to update and harmonise the remuneration proposed in accordance with the enlargement of the list of healthcare professionals, healthcare students and other professionals who may intervene to prescribe, administer and/or inject vaccines against COVID and how they may carry out such procedures;

Whereas the ease of the deployment of self-tests, which does not require the presence of healthcare professionals while requiring support, and their less invasive method of carrying out swabs, will make it possible to carry out more frequent tests; it is thus appropriate to lay down the conditions for the distribution and use of these tests; whereas, in addition, selling price standards must be laid down in order to ensure that the tests are accessible to the general population and to provide for their free availability for certain categories of people which so require; whereas, finally, it is necessary to lay down the conditions for the coverage thereof by health insurance for certain categories of people;

Whereas, in order to accompany the dispensing of these self-tests with pharmaceutical advice, it is necessary to limit this dispensing to pharmacies and to prohibit the sale thereof on the internet; whereas, in order to ensure reliable information, advertising must comply with a specification defined by the National Agency for the Safety of Medicinal and Health Products and advertising intended for the general public must be subject to the prior authorisation of said agency and be limited to pharmacies;

Whereas the mobilisation of clinical laboratories in screening for the epidemic is incompatible with the preparation of accreditation dossiers by 1 May 2021; whereas this date should be extended to 1 November 2021,

Hereby orders:

**Article 1**

The aforementioned Order of 10 July 2020 shall be amended as follows:

1. After Article 16(IV), a V shall be added, worded as follows:

‘V. - In accordance with the provisions of I, II and III of this Article, military hospitals shall be regarded as healthcare establishments. For these hospitals, the fund mentioned in III is the National Military Social Security Fund mentioned in Article L174-15 of the Social Security Code.’;

2. Article 18-1 shall be amended as follows:

a) In the second subparagraph of VI, the word: ‘nurses’ shall be replaced by the words: ‘professionals other than doctors’ and in the fifth subparagraph of the same VI, the words: ‘nurses’ shall be replaced by the words: ‘professionals other than doctors’;

b) VI shall be supplemented by a subparagraph, worded as follows:

‘In accordance with the present VI, military hospitals shall be regarded as healthcare establishments. The vaccination line is defined for these hospitals as a set of doctors, nurses, students and support personnel, mobilised to provide vaccinations within a vaccination centre for a duration of four hours.’;

c) In VII, the words: ‘doctors’ are replaced by the words: ‘private healthcare professionals authorised to bill for a an act of injection of the vaccine against COVID-19’;

3. The table annexed to Article 18-1 shall be replaced by the table annexed to this Order;

4. Article 26-2 is amended as follows:

a) In the second sentence of the first subparagraph of I, the words: ‘may be organised by’ shall be replaced by the words: ‘may only be organised by’;

b) In the first, second and fourth subparagraphs of II, after the words: ‘by self-tests’ the words ‘on nasal swabs’ are inserted;

c) Before the final subparagraph of II, a subparagraph shall be inserted as follows: ‘Pharmacists may advise, dispense and sell in their pharmacy, in vitro diagnostic medical devices intended to carry out self-tests for the antigenic detection of SARS-CoV-2 virus on nasal swabs included in the list referred to in the fourth subparagraph of the present II. These medical devices are reserved for asymptomatic persons over fifteen years of age, for their personal use only.’;

d) In the second sentence of the final subparagraph of II, the words: ‘may be organised by’ shall be replaced by the words: ‘may only be organised by’;

e) IV, V, VI, VII and VIII shall be added as follows:

‘IV.- Self-tests for the antigenic detection of SARS-CoV-2 on nasal swabs referred to in II shall be provided free of charge by pharmacists in pharmacies open to the public to persons in the following categories:

‘- salaried employees of the following home services working with elderly persons or persons with disabilities: Home help and support service (SAAD), Multi-purpose home help and care service for the elderly and/or adults with disabilities (SPASAD), Home nursing care service (SSIAD), Social support service (SAVS), Medical social support service for adults with disabilities (SAMSAH), Special education and home care service (SESSAD);

‘- salaried employees of private employers who work with elderly persons or persons with disabilities for basic day-to-day tasks;

‘- family caregivers mentioned in Article L441-1 of the Social Action and Families Code accompanying elderly persons or persons with disabilities.

‘The free dispensing of self-tests shall be provided upon presentation of proof by the professional and shall be the remunerated by the pharmacist in accordance with the procedures laid down in the table annexed to this Article.

‘For the purposes of this IV, the purchase and dispensing of self-tests by pharmacies open to the public shall be reimbursed and paid by the health insurance in accordance with the procedures laid down in Table 1 annexed to this Article and, where appropriate, after application of a surcharge coefficient referred to in Table 2 of the same Annex.

‘V. - When dispensing or selling these devices, pharmacists shall submit the user’s guide found on the website of the Ministry of Health.

‘VI. - The retail sale and dispensing of in vitro diagnostic medical devices for antigenic detection of the SARS-CoV-2 virus by means of self-tests reserved for the pharmacies in accordance with Article L4211-1 of the Public Health Code cannot be the subject of the electronic commerce activity referred to in Article L5125-33 of the same Code.

‘VII. - The selling prices of in vitro diagnostic medical devices for antigenic detection of the virus by means of self-tests can not exceed, per test and all taxes included, EUR 6.00 until 15 May, or EUR 5.20 thereafter.

‘The wholesale selling prices intended for the resale of the products mentioned in the previous subparagraph can not exceed, per test and all taxes included, EUR 4.70 until 15 May or EUR 3.70 thereafter.

‘VIII. - By way of derogation from the provisions of Articles L5223-2 and L5223-3 of the Public Health Code, the advertising of all self-tests for antigenic detection of the SARS-CoV-2 virus on nasal swabs included in the list published on the website of the Ministry of Health shall be subject to the following provisions:

‘1. Advertising directed at the general public is subject to prior authorisation issued by the National Agency for the Safety of Medicinal and Health Products provided for in Articles L5223-3 et seq. of the Public Health Code in accordance with the conditions and procedures laid down in a specification published on the Agency’s website; it is limited to pharmacists within their pharmacy;

‘2. Advertising directed at health professionals shall in particular comply with the conditions and procedures laid down in a specification published on the same website.’;

5. An Article 28-3 is inserted after Article 28-2, worded as follows:

‘*Article 28-3.* - The deadline for the submission of an application for accreditation relating to the staff lines of a clinical laboratory, established on 1 May 2021 by Article 23(I)(1)(b) of Law No 2020-734 of 17 June 2020 on various provisions relating to the health crisis, other urgent measures and the withdrawal of the United Kingdom from the European Union, shall be extended to 1 November 2021.’

**Article 2**

This Order shall be published in the *Official Journal* of the French Republic.

Dated 10 April 2021.

By the Minister for Solidarity and Health,

Olivier VERAN

ANNEX to Article 18-1

Amounts of rates:

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|  | **Weekdays and Saturday mornings (for 4 hours)** | **Saturday afternoons, Sundays and public holidays (for 4 hours)** |
| **Rate A: -Doctors and hospital professionals other than doctors, retired persons or students -Hospital support workers** | **€ 625** | **€ 1,015** |
| **Rate B: -Hospital doctors, retired persons or students -Private professionals other than doctors -Hospital support workers** | **€ 500** | **€ 800** |
| **Rate C: -Private doctors -Hospital professionals other than doctors, retired persons or students -Hospital support workers** | **€ 340** | **€ 550** |
| **Rate D:**  **-Private doctors -Private professionals other than doctors -Hospital support workers** | **€ 220** | **€ 380** |

ANNEX to Article 26-2(IV)

Table 1: Amount of dispensation allowance paid to pharmacists and unit rate of a self-test reimbursed to health insurance

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| **Beneficiaries of free self-tests** | **Supporting document to be presented for supply** | **Dispensation allowance for pharmacists in EUR** | **Rate of a self-test charged to health insurance in EUR excluding tax** |
| - Salaried employees of home services working with the elderly or persons with disabilities (SAAD, SPASAD, SSIAD, SAVS, SAMSAH, SESSAD);  - Salaried employees of private employers working with elderly persons or persons with disabilities for basic day-to-day tasks;  -Family caregivers mentioned in Article L441-1 of the Social Action and Families Code accompanying elderly persons or persons with disabilities. | A piece of identification, and one of the following support documents:  E-mail or letter sent by the USSRAF [Organisations for the Collection of Social Security and Family Benefit Contributions] (for salaried employees of private employers and family caregivers);  -A pay slip (for home service salaried employees), a Cheques for Universal Employment Services (CESU) pay slip (for employees of private employers) or a copy of the monthly statement of financial compensation (for family caregivers) of less than 3 months. | EUR 1.00 excluding tax for the dispensing to the insured person of 10 self-tests for one month.    Surcharged plus, if applicable, a coefficient for the departments and regions listed in Table 2 | From 12 April 2021 to 15 May 2021  EUR 5.20 per self-test  As of 16 May 2021  EUR 4.20 per self-test  rate plus a coefficient for the departments and regions listed in Table 2 |

Table 2 - Surcharge applicable to the self-test dispensing allowance and to the unit rate of the self-test charged to health insurance

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|  | **Guadeloupe  Saint-Barthélemy  Saint Martin** | **Martinique** | **French Guiana** | **La Réunion** | **Mayotte** |
| Surcharge coefficient applicable to dispensing allowance and the self-test rate | 1.3 | 1.15 | 1.2 | 1.2 | 1.36 |